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A Right Without A Remedy: The Unenforceable Medical Procedure Patent

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COMMENTS

A Right Without a Remedy: The Unenforceable Medical Procedure Patent

I. INTRODUCTION

Buried within the Omnibus Appropriations legislation,[1] enacted in September of 1996, is a radical amendment to the patent code that provokes a philosophical, ethical, constitutional, and pragmatic discussion of patent law and its place in society. The legislation amended the patent code to relieve medical practitioners and related health care entities from liability for infringement of medical procedure patents.[2] With little opportunity for debate, the legislation passed as an impetuous response to a single lawsuit filed to enforce patent rights for a medical procedure patent.

The nucleus of the controversy was a patent infringement lawsuit filed by Dr. Samuel L. Pallin, M.D., against Dr. Jack A. Singer, M.D., and the Hitchcock Clinic for infringement of a patent for a method of making a self-sealing episcleral incision.[3] This infringement action received widespread attention from the media,[4] professional associations,[5] academia,[6] and

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1. Omnibus Consolidated Appropriations Act of 1996, Pub. L. No. 104-208 § 616, 110 Stat. 3009 (codified as amended at 35 U.S.C. § 287 (Supp. II 1996)). Omnibus is

> [a] term frequently used in reference to a legislative bill comprised of two or more general subjects that is designed to compel the executive to approve provisions that he or she would otherwise reject but that he or she signs into law to prevent the defeat of the entire bill.

7 WEST'S ENCYCLOPEDIA OF AMERICAN LAW 383 (1998).

2. *See* 35 U.S.C. § 287(c) (Supp. II 1996).

3. *See* Pallin v. Singer, No. Civ. A. 2:93-CV-202, 1996 WL 274407, at *1 (D. Vt. Mar. 28, 1996) (declaring all claims at issue invalid, instructing Dr. Pallin not to take action to enforce the remaining claims of the patent, finding no infringement, and dismissing with prejudice); Pallin v. Singer, 36 U.S.P.Q.2d (BNA) 1050 (D. Vt. 1995) (denying Dr. Singer's motion for summary judgment of patent validity). The allegedly infringed patent was United States Patent No. 5,080,111, issued January 14, 1992, and entitled *Method of Making Self-Sealing Episcleral Incision.*

4. *See, e.g.*, Carolyn Lederman, M.D., *Pallin Patent Is Invalidated; Ophthalmic Surgeon Samuel Pallin Abandons Patent for Sutureless Cataract Procedure*, OPHTHALMOLOGY TIMES, June 1, 1996, at 10; Greg Borzo, *Method Patent Fails; Court: Surgeon Doesn't Have to Pay Royalties*, AM. MED. NEWS, April 15, 1996, at 1; Michele L. Robinson, *Lawsuit Claiming Medical Procedure Patent Ruled Invalid*, BIOWORLD TODAY, April 15, 1996, at 1; *Judge Rejects Patent for Eye Surgery*, CHI. TRIB., April 2, 1996, at 12; Robert L. Lowes, *Are You Stealing from Other Doctors? (Medical Procedure and Method Patents)*, MED. ECON., March 11, 1996, at 195; Ron Stodghill II, *First, Do*

politicians.[7] Such a diversity of respondents offering commentary, though not altogether unprecedented, is certainly rare for this congenial legal practice area. Indeed, the only "press" generally enjoyed by patents or patent law is due to either occasional massive infringement remedies or published settlements.

Within two years of *Pallin v. Singer*,[8] Congress amended the patent code purportedly to protect the public interest and restore ethical tranquility to the medical profession[9]—at least with regard to patenting medical procedures that do not involve drugs or medical devices.[10] Currently, 35 U.S.C. § 287(c) provides in part:

With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under § 271(a) or (b) of this title, the provisions of §§ 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.[11]

No Harm. Then, Get a Patent: Should Surgical Techniques Be Given Protection, BUS. WK., July 24, 1995, at 86; *Bill Would Stop Method Patents: Urologists Give Bill Strong Support*, UROLOGY TIMES, August 1, 1995, at 1; Sally Squires, *AMA Condemns Patents for Medical Procedures*, WASH. POST, June 20, 1995, at A1.

5. The professional organizations that significantly commented on this issue include the American Bar Association (ABA), American Intellectual Property Law Association (AIPLA), Intellectual Property Owners, American Medical Association (AMA), American Society of Cataract and Refractive Surgery, and American Academy of Ophthalmology.

6. *See, e.g.*, Eric M. Lee, *35 U.S.C. § 287(c): The Physician Immunity Statute*, J. PAT. & TRADEMARK OFF. SOC'Y 701 (1997); Chris J. Katopis, *Patients v. Patents?: Policy Implications of Recent Patent Legislation*, ST. JOHN'S L. REV. 329 (1997); Gregory F. Burch, Note, *Ethical Considerations in the Patenting of Medical Processes*, TEX. L. REV. 1139 (1987).

7. *See* 142 CONG. REC. S11838, S11843-45 (daily ed. Sept. 30, 1996) (statement of Senator Hatch); 142 CONG. REC. S11845, S11845-46, S11847-48 (daily ed. Sept. 30, 1996) (statement of Senator Hatch); 142 CONG. REC. S12023, S12023 (daily ed. Sept. 30, 1996) (statement of Senator Frist); 141 CONG. REC. S15290, S15291-92 (daily ed. Oct. 18, 1995) (statement of Senator Frist); 140 CONG. REC. E1754, E1754 (daily ed. Aug. 17, 1994) (extension of remarks by Representative John Bryant of Texas).

8. No. Civ. A. 2:93-CV-202, 1996 WL 274407, at *1 (D. Vt. March 28, 1996).

9. *See* 142 CONG. REC. S12023, S12023-24 (daily ed. Sept. 30, 1996) (statement of Senator Frist noting that if health care professionals could be sued, "health care costs would explode[,]" patients' privacy would be jeopardized, free dissemination of information would be undermined, and all aspects of medical practice would be regulated by the FDA); *see also* 140 CONG. REC. E1754, E1754 (daily ed. Aug. 17, 1994) (extension of remarks of Representative John Bryant commenting that medical procedures are not patentable subject matter, would result in increased health costs, and would pressure physicians to delay or refrain from using surgical techniques).

10. Apparently, the medical device and pharmaceutical industries have a stronger lobby than the American Medical Association.

11. 35 U.S.C. § 287(c)(1) (Supp. II 1996). The amendment defines "medical activity" as "the performance of a medical or surgical procedure on a body." *Id.* § 287(c)(2)(A). However, "medical activity" does not include "the use of a patented machine, manufacture, or composition of matter in violation of such patent;" "the practice of a patented use of a composition of matter in violation of

Essentially, Congress provided medical practitioners and related health care entities with a statutory exemption from liability for infringement of medical procedure patents. In other words, the United States Patent and Trademark Office (PTO) will grant a patent for a medical procedure, but the patent owner cannot enforce it against likely infringers.[12]

This Comment surveys the events that led to the rash amendment to the patent laws and examines the controversy regarding the realities and purposes of patent rights and medical procedure patents, and the compelling ethical arguments. Part II provides a brief survey of patent law and the patentability of inventions. Part III examines the history of medical process patents and addresses the controversy surrounding such patents. Part IV offers an analysis of the current law. Finally, Part V demonstrates how the current patent laws are adequate to encompass medical procedure patents and rejects racing to a *sui generis* solution. This Comment intends to encourage further debate and express support for a reconsideration and reformation of the legislative recent changes to the patent code.

It would be disingenuous not to admit that the ethical considerations are compelling. This Author fully believes, however, that the correct resolution was not to submarine exigent legislation an amendment that contradicts patent economics and theory, thereby striping patent owners of their patent rights and casting aside the due process that such a material revision to the patent code deserves.[13]

II. PATENT LAW

Generally, the Italian renaissance recognized the benefits of incentive—based innovation and afforded significant protection to inventors.[14] Early in its inception, the United States also recognized the necessity of encouraging

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such patent;" and "the practice of a process in violation of a biotechnology patent." *Id.* § 287(c)(2)(A)(i)-(iii). The exception for "patented use of a composition of matter" does not include "a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter where the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method." *Id.* § 287(c)(2)(F).

12. Other bars to enforcement are equitable in nature, rather than ethical, including laches, estoppel, inequitable conduct, patent misuse, experimental use, personal use, first sale, implied license, and lack of notice (e.g., improper marking per 35 U.S.C. §§ 287, 292). *See* 35 U.S.C. §§ 287, 292 (1994 & Supp. II 1996). Further, the Federal Circuit recently confirmed that patents are enforceable against states. *See* College Sav. Bank v. Florida Prepaid Postsecondary Educ. Expense Bd., 148 F.3d 1343, 47 U.S.P.Q.2d (BNA) 1161 (Fed. Cir. 1998).

13. Indeed, "[i]n no other field would one suggest that the incentives of the patent system be eliminated in the hope that technical progress would proceed unabated." 142 CONG. REC. S11845, S11845 (daily ed. Sept. 30, 1996) (statement by Senator Orrin G. Hatch).

14. *See* DONALD S. CHISUM, ET AL., PRINCIPLES OF PATENT LAW 10 (1998) [hereinafter PRINCIPLES OF PATENT LAW].

innovation and invention. The founding fathers specifically provided for patent laws in the Constitution[15] and promptly promulgated the first statutes in 1790. Since, the patent statute underwent several revisions and moved away from the court's suspicion of patent monopolies evidenced in early patent decisions.[16] The current statute was ratified in 1952 and provides several basic requirements that an invention must meet to be patentable, including statutory subject matter,[17] utility,[18] novelty,[19] and nonobviousness.[20]

The first challenge for a patent application is satisfying statutory subject matter.[21] Specifically, patentability requires that the subject matter of the application is a "new and useful process,[22] machine, manufacture, or composition of matter, or any new and useful improvement thereof. . . ."[23] In the Nineteenth Century, the initial argument raised against patenting medical procedures was that medical procedures were unpatentable subject matter.[24] The PTO, Supreme Court, and Federal Circuit opinions, however, confirm

15. The Constitution specifically provides that Congress has the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . . ." U.S. CONST. art. I, § 8, cl. 8.

16. Indeed, Justice Jackson once stated in a dissent that "the only patent that is valid is one which this Court has not been able to get its hands on." Jungersen v. Ostby & Barton Co., 335 U.S. 560, 572, 80 U.S.P.Q.2d (BNA) 32, 36 (1949) (Jackson, J., dissenting). To this I would add that *the only patent enforceable is one that a special interest group has not been able to get its hands on.*

17. *See* 35 U.S.C. § 101 (1994).

18. *See id.*

19. *See id.* § 102.

20. *See id.* § 103.

21. *See id.* § 101.

22. "The term 'process' means process, art or method, and includes a new use of a known process . . . ." 35 U.S.C. § 100(b). In 1790, Congress enacted the first Patent statute and authorized patents for "any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used." Act of April 4, 1790. In 1793, Congress reconsidered patentable subject matter and authorized patents for "any useful art, machine, manufacture, or composition of matter, or any new and useful improvement, not known or used before the application." Act of Feb. 21, 1793. The four categories recited in the 1793 statute are still used to describe the classes of patentable subject matter, except in the 1952 Patent Act the term "process" replaced "art." "Art" and "process" are considered to have the same meaning. *See* Diamond v. Diehr, 450 U.S. 175, 181-82 & nn.6-7, 209 U.S.P.Q. (BNA) 1, 6-7 & nn.6-7 (1981) ("Although the term 'process' was not added to 35 U.S.C. § 101 until 1952 a process has historically enjoyed patent protection because it was considered a form of 'art' as that term was used in the 1793 Act."); Corning v. Burden, 56 U.S. (15 How.) 252, 267 (1853) ("A process . . . is included under the general term 'useful art.'"); S. REP. NO. 82-1979, at 5, 17 (1952), *reprinted in* 1952 U.S.C.A.A.N. 2394, 2398-99, 2409; H.R. REP. NO. 82-1923, at 17 (1952). The replacement of "art" by "process" in 1952 may have led to the recognition of medical procedure patents. Arguably, processes were always patentable as "art," but this clarification and subsequent court decisions effectively overruled the proposition that medical processes could not be patented. *Cf. Diehr*, 450 U.S. at 182, 209 U.S.P.Q. (BNA) 1, 6 (1981).

23. 35 U.S.C. § 101.

24. *See* text *infra* Section III.A.

that medical procedures are patentable subject matter. Although "Congress plainly contemplated that the patent laws whould be given wide scope, . . . [t]his is not to suggest that §101 has no limits or that it embraces every discovery."[25] Limitations to patentable subject matter have repeatedly been stated as the laws of nature, physical phenomena, and abstract ideas (including mathematical formula or algorithms).[26] Notwithstanding these limitations, the Supreme Court stated that Congress intended statutory subject matter to extend to "anything under the sun that is made by man."[27] Because medical procedure patents constitute statutory subject matter, the legislation resorted to prohibiting patent owners from enforcing their right to collect damages for infringement.

Second, an invention must be useful.[28] Specifically, an invention must do something, perform its intended function, and provide some benefit to society.[29] In other words, inventions that do not work, or work to inflict harm, do not satisfy the utility requirement.[30]

Third, an invention must be novel or contribute something new to society.[31] In general, an invention is not patentable if the subject matter has already been known, used, or invented in the United States, or patented or described in a printed publication anywhere in the world.[32]

Fourth, an invention must be "nonobvious."[33] In general, an invention is "obvious" when it would have been obvious to a person having ordinary skill in the art when considering the problem at hand and the prior art.[34]

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25. Diamond v. Chakrabarty, 447 U.S. 303, 308, 206 U.S.P.Q. (BNA) 193, 197 (1980).

26. *See id.* at 309, 206 U.S.P.Q. (BNA) at 198. The most recent decision from the Federal Circuit substantially addressing statutory subject matter, however, confirmed that mathematical formula or algorithms that are programmed in a general purpose computer is patentable subject matter. *See* State Street Bank & Trust Co. v. Signature Fin. Group, Inc., 149 F.3d 1368, 1373-74, 47 U.S.P.Q.2d (BNA) 1596, 1601-02 (Fed. Cir. 1998). Also, *State Street Bank* laid to rest the so-called business method exception. *See id.* at 1375, 47 U.S.P.Q.2d (BNA) at 1602-03. Thus, a fair generalization of *State Street Bank* is that patentable subject matter is no longer a relevant issue, that is, unless Congress acts again and makes it so.

27. *Chakrabarty*, 447 U.S. at 309, 206 U.S.P.Q. (BNA) at 198.

28. *See* 35 U.S.C. § 101.

29. *See generally* PRINCIPLES OF PATENT LAW, *supra* note 14, at 729.

30. Without a doubt, medical procedures provide a benefit to society and can be considered "useful."

31. *See* 35 U.S.C. §§ 102(a), (e), (g).

32. *See id.*

33. *See id.* § 103 In the case of medical procedures, obviousness references may be found in the many journals and publications throughout the world. Further, procedures used, but not abandoned, suppressed, or concealed, are obviousness references.

34. Nonobviousness analysis makes four basic inquiries: (1) the scope and content of the prior art are determined; (2) the differences between the prior art and the claims at issue are ascertained; (3) the level of ordinary skill in the pertinent art is resolved; and (4) secondary considerations are

III. THE CONTROVERSY OVER MEDICAL PROCEDURE PATENTS

A. Early Attitudes Toward Medical Procedure Patents

Early cases and congressional action questioned the patentability of medical procedures, rather than allowing enforcement. The early justification for prohibiting the patenting of medical procedures stemmed from the scope of statutory subject matter. As noted earlier, the scope of patentable subject matter has greatly expanded and no longer provides a bar for medical procedures; instead, opponents resorted to congressional action to render them unenforceable.

Case law that addresses the dispute dates back to the last century in *Morton v. New York Eye Infirmary*, where a patent owner sought to recover damages due to infringement of a patent for a procedure of administering ether to surgical patients as an anaesthetic.[35] Although the existence of ether's intoxicating effect on animals was well known to chemists, the discovery was alleged to be that inhalation of increased quantities of ether causes a state of complete insensibility to pain.[36] The inventors then claimed as their invention the combination of the painless state and surgical operations.[37] The trial court, however, directed the jury to find for the defendant.[38] The court admitted that the invention was "among the great discoveries of modern times," but nonetheless denied plaintiff's motion for a new trial.[39] The court rested its decision on grounds that the patent was obvious and not novel, but implied that medical and surgical procedures were not patentable processes.[40] Further, the court reasoned that the patentees attempted to "shelter the discovery under . . . terms of the patent act which protect 'any new and useful improvement on any art'" by combining the discovery with surgical operations.[41] While not patentable subject matter, the court noted that the

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weighed in light of circumstances. *See* Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 U.S.P.Q. (BNA) 459, 465-67 (1966).

35. *See* 17 F. Cas. 879 (C.C.S.D.N.Y. 1862).

36. *See id.* at 882 ("The effect discovered was produced by old agents, operating by old means upon old subjects. The effect alone was new, and to that only can the term 'discovery' apply.").

37. *See id.*

38. *See id.* at 881. The trial judge suspended the trial to hold a hearing on the issue as to whether the subject matter of the invention was patentable. *See id.*

39. *See* Morton v. New York Eye Infirmary, 17 F. Cas. at 883-84.

40. *See id.* at 882-84. Specifically, the court stated that "[n]either the natural functions of an animal upon which or through which it may be designed to operate, nor any of the useful purposes to which it may be applied, can form any essential parts of the combination, however they may illustrate and establish its usefulness." *Id.* at 884.

41. *Id.* at 882 ("It was clearly not the discovery or invention of an 'art,' or 'machine,' or

invention was useful, nonobvious, and novel.[42] Thereafter, courts interpreted *Morton* to prohibit the patenting of any medical procedures.[43]

Several years later, the Patent Office Board of Appeals in *Ex parte Brinkerhoff* relied on *Morton* and affirmed a rejection of a patent application for a medical procedure for treating animal tissue that utilized prior art.[44] The Board held that "[t]he methods or modes of treatment of (sic) physicians of certain diseases are not patentable" on the rationale that "to grant a patent for a particular method of treatment would have a tendency to deceive the public by leading it to believe that the method therein described and claimed would produce the desired result in all cases."[45] In other words, the uncertainty that goes along with the success of medical procedures makes the process unpatentable subject matter because the public would wrongfully equate patentability with superior quality and likelihood of medical success.[46]

Subsequent decisions by the Board did not wholly adopt the rule from *Brinkerhoff*.[47] In *Ex parte Kettering*, the Board found that the claims for a method and an apparatus for artificially producing a fever in the human body

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'manufacture,' or 'composition of matter.' Nor was it an 'improvement' on any one of the last three. It was, therefore, called, in substance, an improvement in the art of surgery.").

42. *See id.* at 882-83.

43. *See infra* text accompanying notes 47-65.

44. *See Ex parte* Brinkerhoff, 27 J. PAT. OFF. SOC'Y 797 (1945) (reviewing 24 Comm'n Manuscript Decision 349 (Pat. Off. Bd. App. 1883) (Case No. 182)).

45. *Id.* at 798.

46. This rationale seems rooted in the utility requirement of 35 U.S.C. § 101, which requires that an invention work for its intended purpose. This argument, however, is weak. Perhaps the court in *Brinkerhoff* recognized it as so and therefore did not expressly rely on it. Many inventions do not provide "certainty" in their result, and medical devices are one example. Medical devices have long been considered patentable subject matter and enforceable, yet should inherit the same uncertainty that medical procedures have.

The acceptance of uncertainty in medicine has not always been the case. At the beginning of the medical technology revolution, many physicians and scholars resisted the innovations. *See Technology and the Eclipse of Individualism, in* IN SEARCH OF THE MODERN HIPPOCRATES: THE FUTURE FOR PHYSICIANHOOD 214-16 (Roger J. Bulger ed., 1987) [hereinafter MODERN HIPPOCRATES]. Although the prevailing notion was that "machine-generated and laboratory evidence stood for exactness and precision—for science; [and] that clinical evidence stood for diversity and vagueness—for empiricism[;] ... physicians attributed levels of accuracy to the technology that it did not have." *Id.* at 215-16. "What doctors then as now remained generally unaware of was the large rate of error associated with machines and their users—15 to 20 percent on the average, as revealed by a 1975 study." *Id.* at 216 (citing L.M. Koran, *The Reliability of Clinical Methods, Data and Judgments*, NEW ENG. J. MED. 293, 700 (1975)).

47. *See, e.g., Ex parte* Scherer, 103 U.S.P.Q. (BNA) 107, 109-10 (Pat. & Trademark Off. Bd. App. 1954) (citing *Ex parte* Kettering, 35 U.S.P.Q. (BNA) 342 (Pat. Off. Bd. App. 1936); *Ex parte* Wappler, 26 U.S.P.Q. (BNA) 191 (1934)); *see also* 1 DONALD S. CHISUM, CHISUM ON PATENTS § 1.03[3], at 1-72 (1997) [hereinafter CHISUM ON PATENTS] (citing Recent Cases, *Patents: Method of Treatment of Human Body Held Patentable*, 23 GEO. WASH. L. REV. 238, 238 (1954); Dr. I.J. Fellner, *Patentability of Therapeutic Methods*, 28 J. PAT. OFF. SOC'Y 90 (1946)).

were an improvement over the prior art and thus entitled to patent protection.[48] In reaching this conclusion, the Board distinguished *Kettering*'s invention from that in *Brinkeroff* because its purpose "has no direct relation to the curing of a particular disease"[49] despite having an "ultimate purpose of . . . cur[ing] a disease."[50] Moreover, the results were "sufficiently certain" as to avoid *Brinkerhoff*'s reliance on the uncertainty of medical procedures rationale.[51] Similarly, in *Ex parte Wappler*, the Board found that claims to a method of shrinking living tissue were entitled to patent protection.[52] The Board in *Wappler* distinguished the invention from that in *Morton* and *Brinkerhoff*, and found it to be merely a process as defined in *Cochrane v. Deener*[53] because the results were "sufficiently certain."[54] Nevertheless, the PTO and courts were initially reluctant to extend the patent laws to processes in general, despite Congress' replacement of "art" with "process" in 1952.[55]

In 1954, the Board of Patents Appeals in *Ex parte Scherer* overruled *Brinkerhoff*'s holding that medical procedures were not patentable.[56] The Board ruled that the invention was a useful process under § 101,[57] and that "medical or surgical" processes or methods are patentable.[58] The Board distinguished *Morton* on the grounds that *Morton* may be read to be a patentability rejection due to lack of novelty or obviousness.[59] Further, *Morton*'s "uncertainty" justification was dismissed as "more properly considered under the [separate and distinct requirement] of utility."[60] The

48. *Kettering*, 35 U.S.P.Q. (BNA) at 343.

49. *Id.*

50. *Id.*

51. *See id.*

52. *Wappler*, 26 U.S.P.Q. (BNA) at 192.

53. 94 U.S. 780, 788 (1877) ("A process is a mode of treatment of certain materials to produce a given result. It is an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing. If new and useful, it is just as patentable as is a piece of machinery.").

54. *See Wappler*, 26 U.S.P.Q. (BNA) at 192.

55. Although the issue was passed over by the PTO, the Supreme Court stated that the change from art to process did not significantly alter its judicial interpretation. *Compare Brinkerhoff*, 27 J. PAT. OFF. SOC'Y at 798, *with* Diamond v. Diehr, 450 U.S. 175, 182, 209 U.S.P.Q. (BNA) 1, 6 (1981).

56. *See Ex parte* Scherer, 103 U.S.P.Q. (BNA) 107 (Pat. Off. Bd. App. 1954). The invention concerned a method of injecting medicine by a pressure jet and without the use of a conventional hypodermic needle. *See id.* at 108. The injection was accomplished by a high pressure stream of fluid passing through a minute orifice sufficient to pass through the skin and underlying tissue. *See id.*

57. *Id.* at 109.

58. *See id.* at 110.

59. *See id.*

60. *See id.*

Board, however, expressly overruled *Brinkerhoff* "[t]o the extent that [it] holds or implies that all medical or surgical methods are unpatentable subject matter merely because they involve treating the human body."[61]

In addition to occasional litigation over the patentability of medical procedures,[62] there was legislative activity as early as 1902[63] to exclude medical procedures from patentable subject matter. In 1903, a similar bill[64] was introduced but failed to pass. After failures in 1902 and 1903, Congress lost interest in excluding medical procedures from statutory subject matter.[65]

Until recently, professional associations has followed the position favored by the courts and PTO.[66] In 1948, prior to the PTO's reversal of *Brinkerhoff* and its position on the patentability of medical processes, the American Medical Association (AMA) acknowledged that investment and research in medical processes and devices needed adequate protection.[67] Moreover, the AMA Judicial Council issued an Official Opinion stating that the AMA did not consider medical process patents unethical.[68]

B. Pallin v. Singer

As previously noted, this recent hyperbole regarding medical procedure patents was sparked by *Pallin v. Singer*, the first known lawsuit to enforce a medical procedure patent. The lawsuit did not create the controversy, but merely revived an old one. The facts of the case are relatively simple. Dr. Samuel Pallin sued several of his peers for infringement of his patent for a sutureless, cataract surgery technique.[69] According to Dr. Pallin, this

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61. *Scherer*, 103 U.S.P.Q. (BNA) at 110.

62. *See supra* notes 35-61 and accompanying text.

63. *See* William D. Noonan, *Patenting Medical Surgical Procedures*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 651, 654 (1995) (citing H.R. 12451 (1902)). Specifically, the legislation prohibited patents on the "art of treating human disease . . . or upon any device adapted to be used in the treatment of human disease or disability, or attached to the human body and used as a substitute for any lost part thereof, or upon any art of making such device . . . ." *Id.*

64. *See id.* (citing H.R. 13679 (1903)).

65. *See* HOWARD FORMAN, LAW OF CHEMICAL, METALLURGICAL AND PHARMACEUTICAL PATENTS 64-71 (1967), *cited in* Noonan, *supra* note 63, at 654.

66. On the other hand, one could argue that it is actually the other way around. Before 1948, courts ruled against medical procedure patents. After the PTO recognized their patentability, the American Medical Association (AMA) also accepted their merit. In the 1990s, however, the medical professional associations lead the revolution by arguing strongly against medical procedure patents, and the courts followed suit. Thus, the dog and tail alternatively wag each other.

67. *See* Noonan, *supra* note 63, at 655; *Official Opinions of the Judicial Council*, 163 JAMA 1156, 1157 (1957) [hereinafter *Official Opinions*].

68. *See Official Opinions*, *supra* note 67, at 1157 ("It is not unethical [in itself] for a physician to patent a surgical or diagnostic instrument he has discovered or developed. Our laws governing patents are based on the sound doctrine that one is entitled to protect his discovery.").

69. Dr. Pallin alleged that the defendants performed hundreds of operations that infringed his

technique saved $17 per operation and costed a minimal royalty or license fee.[70] The district court denied defendants' motion for summary judgment on the grounds that defendants failed to prove that there was no issue of material fact as to whether the prior art fully anticipated the patented invention and whether the invention was obvious.[71] Ultimately, the court issued a consent judgment on March 28, 1996, declaring the four asserted claims invalid, prohibiting Dr. Pallin from enforcing the remaining claims, and declaring the defendants did not infringe the remaining claims considered not invalid.[72]

C. The Response

One of the perplexing aspects of the Pallin v. Singer decision was the response from Congress and the patent and medical community.[73] For example, the professional associations reversed their position and condemned medical procedure patents. Similarly, Congress acted contrary to its earlier

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patent and induced others to infringe by teaching others to perform the patented procedure. *See* Pallin v. Singer, 36 U.S.P.Q.2d (BNA) 1050, 1051 (D. Vt. 1995). The patent described a technique of making a substantially self-healing, chevron-shaped incision into the eye (to allow the replacement of the lens). *See id.* at 1050-51. *See* United States Patent No. 5,080,111. The cataract surgery at issue replaced a cloudy, ineffective lens with a plastic replacement. *Id.* at 1050. Traditionally, the incision was closed by sutures to prevent wound separation; however, sutures often led to an astigmatism. *See id.*

70. The royalties per operation demanded by Dr. Pallin were minimal. By most accounts, the royalty for the procedure was four or five dollars, but saved seventeen dollars over the old method. *See, e.g.*, 142 CONG. REC. S11845, S11847 (daily ed. Sept. 30, 1996); 142 CONG. REC. S11838, S11844 (daily ed. Sept. 30, 1996); 142 CONG. REC. S12023, S12023 (daily ed. Sept. 30, 1996); *Medical Procedures Innovation and Affordability Act and the Inventor Protection Act of 1995: Hearings on H.R. 1127 Before the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, 104th Cong. 39, 41 (1995) [hereinafter *Medical Procedures Hearings*], *reprinted in* 1995 WL 615761 (statement of Samuel L. Pallin, M.D., F.A.C.S., Medical Director, Lear Eye Clinic, Scottsdale, Arizona); Edward Felsenthal, *Medical Patents Trigger Debate Among Doctors*, WALL ST. J., Aug. 11, 1994, at B1. *But cf. Medical Procedures Hearings*, *supra*, at 45, *reprinted in* 1995 WL 615749 (statement of Jack A. Singer, M.D., Dartmouth-Hitchcock Medical Center, Randolph, Vermont, stating that "Dr. Pallin originally demanded a royalty of $2,500 to $10,000 per year, which could be increased annually at his discretion").

71. *See Pallin*, 36 U.S.P.Q.2d (BNA) at 1053-54. Specifically, the defendants alleged that others had performed the operation prior to the date of invention. *See id.* at 1051.

72. *See* Pallin v. Singer, Civ. A. No. 2:93:CV-202, 1996 WL 274407, at *1 (D. Vt. Mar. 28, 1996).

73. One periodical informally surveyed doctors and medical groups, and compared the arguments as recited by doctors that favor patenting medical procedure with the arguments stated by medical groups opposed to patenting medical procedures. *See* Stodghill, *supra* note 4, at 87. The article indicates that the doctors that favor patents do so because they "[p]rovide incentive to doctors to fund research efforts," "[e]nable physicians to benefit financially from medical discoveries," and "[b]roaden channels for professional recognition." Conversely, the medical groups oppose patents because patents "[i]nhibit access to new medical innovations and reduce quality of care," "[d]rive up health-care costs by imposing licensing fees on physicians," and "invite abuse by physicians making spurious claims for protection." *Id.*

position. There was not, however, a unilateral condemnation, and several important players did not concur.

Following *Pallin v. Singer*, the AMA completely reversed its previous position on medical procedure patents acknowledging that medical procedure patents were justified by the expenses incurred by medical researchers.[74] The AMA House of Delegates quickly voted to condemn medical procedure patents.[75] Likewise, the American Academy of Ophthalmology condemned medical procedure patents and urged support for legislation prohibiting enforcement of such patents.[76]

The response from the medical community and Congress was astounding. Heavy lobbying by the AMA and several politicians provoked Congress into displaying rarely seen legislative speed and agility. Following *Pallin*, professional associations, Congress, and other interested parties saw a chance to make a change by attaching an amendment to the Omnibus Appropriations bill that was working its way through the Senate and House of Representatives, essentially carving out medical procedure patents from statutory subject matter. Within seven months of the consent judgment in *Pallin v. Singer*, President Clinton signed legislation that effectively nullified medical process patents by prohibiting enforcement against a medical

74. *See Official Opinions*, *supra* note 67, at 1157 ("It is not unethical [in itself] for a physician to patent a surgical or diagnostic instrument he has discovered or developed. Our laws governing patents are based on the sound doctrine that one is entitled to protect his discovery."). *But cf.* JOHN P. KENNY, PRINCIPLES OF MEDICAL ETHICS 45 (1952) (stating that one of the duties to the profession "concerns the obligation of not commercializing the medical profession . . . [and] precludes any remuneration from patents and copyrights [because] they are directly contrary to the nature of the medical profession.").

75. *See* American Medical Association, *Resolution No. 2: Patents for Medical Diagnostic and Therapeutic Techniques, in* HOUSE OF DELEGATES PROCEEDINGS, 144TH ANNUAL MEETING 388, 390 (1994) ("RESOLVED, That our American Medical Association vigorously condemn the patenting of medical and surgical procedures and work with Congress to outlaw this practice."). Then, at the 1995 annual meeting, the Council on Ethical and Judicial Affairs issued a report on the implications of patenting medical procedures. *See* American Medical Association, *Reports of Council on Ethical and Judicial Affairs, Patenting of Medical Procedures, in* HOUSE OF DELEGATES PROCEEDINGS, 144TH ANNUAL MEETING 200 (1995) [hereinafter 1995 AMA Report]. The AMA set forth four arguments against patenting of medical procedures: (1) patients' access to medical procedures would be restricted, causing use of inferior procedures and chilling of information dissemination; (2) health care costs would increase; (3) patient confidentiality would be abated; and (4) patents are not needed for incentive to innovate. *See id.*; *see also* Noonan, *supra* note 63, at 655.

76. *See* H. Dunbar Hoskins, Jr., M.D., *Doctors' Group Opposes Medical Method Patents*, WALL ST. J., Sept. 6, 1994, at A13 (letter to the editor, by the Executive Vice President of the American Academy of Ophthalmology, in which he wrote "[m]ethod patents are contrary to fundamental tenets of medicine: that physicians have an obligation to share their knowledge and skills for the benefit of humanity."); *see also American Academy of Ophthalmology—Medical Procedure Patents* (visited Oct. 29, 1997) <http://www.eyenet.org/members/activities/patents.html>.

practitioner or a related health care authority.[77] Luckily for the supporters of the legislation, the appropriations bill was nearing completion and would not be held up because of a single, albeit objectionable, amendment.[78]

The Gaske/Frist amendment prohibiting enforcement of medical process patents was attached to the Omnibus Consolidated Appropriations Act.[79] When such a bill works its way through committees and floors of the House of Representatives and Senate,[80] it is not uncommon for incidental legislation to be attached.[81] Congresspersons know that certain amendments can be attached without holding up the passing of a major piece of legislation.[82] Indeed, such legislation oftentimes would not otherwise pass.[83] Nevertheless, the Ganske/Frist amendment met significant opposition, particularly in the Senate. Several Senators recognized the dire need for the changes to the

77. President Clinton signed the legislation on September 30, 1996, which is codified in 35 U.S.C. § 287 as subsection (c). *See* 35 U.S.C. § 287(c) (Supp. II 1996). Despite signing the legislation, President Clinton and his administration opposed the amendment to § 287. *See* 142 CONG. REC. S11845, S11845-46 (daily ed. Sept. 30, 1996).

78. *See, e.g.*, WILLIAM J. KEEFE & MORRIS S. OGUL, THE AMERICAN LEGISLATIVE PROCESS: CONGRESS AND THE STATES 245 (8th ed. 1993). A "quirk" of the amending process is the "legislative rider," which "refers to an irrelevant amendment—one that is tacked onto a bill well on its way to passage. Unlikely to make it on its own for one reason or another, the amendment rides into law as part of another measure. Typically, a rider is attached to an appropriation bill... [because there are] enormous pressures ... to accept the bill, rider and all, rather than to jeopardize a program." *Id.*

79. The specific legislation within the appropriations bill was the Ganske/Frist amendment, named after Representative Greg Ganske and Senator Bill Frist. In March of 1995, Representative Ganske introduced legislation that would explicitly exclude medical process patents from being patentable subject matter unless such a process was a necessary component of a patentable medical device, but it was deemed undefined in scope. *See Bill with PTO Funding and Patent Reform on Medical Procedures Is Signed into Law*, BNA PAT., TRADEMARK, & COPYRIGHT L. DAILY, Oct. 7, 1996 [hereinafter *Bill Signed*]; *see also* 142 CONG. REC. S12023, S12023 (Sept. 30, 1996). In Oct. of 1995, Senator Frist introduced legislation that exempted medical practitioners and related health care entities from infringement liability, but did not exclude the pharmaceutical or medical device industry. *Id.* In early September of 1996, Representative Ganske, Senator Frist, and the biotech and medical communities reached a compromise, which later became the legislation at issue. *See id.*

80. *School House Rock: I'm Just a Bill—How a Bill Becomes a Law* (Capitol Cities/ABC Video Publishing, Inc. 1995)

81. *See* KEEFE & OGUL, *supra* note 78, at 245; *see also* WALTER J. OLESZEK, CONGRESSIONAL PROCEDURES AND THE POLICY PROCESS 157-58, 232-33 (3d ed. 1989).

> Riders often encompass proposals that are less likely to become law on their own merits (as separate bills), either because of resistance in the Senate or the probability of a presidential veto. The strategy on such issues is to draft them as riders to important legislation—"must' bills that are almost certain to be enacted—such as appropriations measures funding the federal government...."

OLESZEK, *supra*, at 158.

82. *See* KEEFE & OGUL, *supra* note 78, at 245; OLESZEK, *supra* note 81, at 157-58, 232-33.

83. *See* KEEFE & OGUL, *supra* note 78, at 245; OLESZEK, *supra* note 81, at 158.

patent law being proposed, and that such a change justified substantially more consideration than afforded by "back door" enactment.[84]

Notwithstanding the absence of congressional consideration in the Senate, the House of Representatives conducted hearings before the Subcommittee of Legislative and International Affairs. Those testifying included Dr. Samuel Pallin and Dr. Jack Singer (of *Pallin v. Singer*),[85] Clinton Administration representatives,[86] the American Bar Association,[87] the American Intellectual Property Law Association,[88] judges,[89] professional medical associations,[90] and Dr. William Noonan.[91] The general arguments made in support of the legislation were not original, but rather a revival of the arguments raised by Congress about the patentability of medical procedures ninety years ago.[92]

In sum, the backdoor enactment of the Ganske/Frist amendment has left many unfought battles over an issue that splits agencies, professional associations, and politicians. Changes to the patent law having an equivalent philosophical and substantive impact are rare. One would have to go back many years to find such a significant alteration to the patent code. The

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84. Senator Orrin G. Hatch, Chair of the Judiciary Committee, William V. Roth, Jr., Chair of the Finance Committee, and the United States Trade Representative were among those who spoke against the "back door" amendment. *See Bill Signed, supra* note 79. Besides Senator Hatch, other opponents to the legislation included the PTO, American Bar Association, Clinton Administration, Intellectual Property Owners Association, American Medical Association, and Pharmaceutical Research and Manufacturers of America. *See* 142 CONG. REC. S11838, S11843-45 (daily ed. Sept. 30, 1996); 142 CONG. REC. S11845, S11845-47 (daily ed. Sept. 30, 1996). Proponents of the amendment also had support from the American Medical Association and the American Society of Cataract and Refractive Surgery. *See* 140 CONG. REC. E1754, E1754 (daily ed. Aug. 17, 1994).

85. *See Medical Procedures Hearings, supra* note 70, at 38-51, *reprinted in* 1995 WL 615761 & 615749 (statements and testimonies of Samuel L. Pallin, M.D., F.A.C.S. and Jack A. Singer, M.D.).

86. *See* 142 CONG. REC. S11845, S11845-46 (daily ed. Sept. 30, 1996) (including opposition to bill by Bruce Lehman, Commissioner of Patents and Trademarks).

87. *See Medical Procedures Hearings, supra* note 70, at 76-87, *reprinted in* 1995 WL 615780 (statement of Donald R. Dunner, Chair of Intellectual Property Section).

88. *See* 142 CONG. REC. S11845, S11846 (daily ed. Sept. 30, 1996); *Medical Procedures Hearings, supra* note 70, at 87-92, *reprinted in* 1995 WL 615737 (statement of Michael K. Kirk, Executive Director of the American Intellectual Property Law Association).

89. *See* 140 CONG. REC. E1754, E1754 (daily ed. Aug. 17, 1994) (remarks by Representative John Bryant of Texas).

90. *See Medical Procedures Hearings, supra* note 70, at 53-61, *reprinted in* 1995 WL 615751 (statement of Charles D. Kelman, M.D., American Society of Cataract and Refractive Surgery).

91. *See Medical Procedures Hearings, supra* note 70, at 61-67, *reprinted in* 1995 WL 615750 (statement of William D. Noonan, M.D.).

92. *See Medical Procedures Hearings, supra* note 70, at 28-38, *reprinted in* 1995 WL 615779 (statement of G. Lee Skillington, Office of Legislative and International Affairs, U.S. Patent and Trademark Office). The 1902 and 1903 bills were never enacted and it cannot be said that the parade of horrors ever materialized. *See* Noonan, *supra* note 63, at 654; *see generally Medical Procedures Hearings, supra* note 70, at 28-38, *reprinted in* 1995 WL 615779 (statement of G. Lee Skillington).

dispute has a distinct, palpable line that is ripe for intellectual, philosophical, and ethical debate and resolution.

D. The Current State of the Law

On September 30, 1996, President Clinton signed the Omnibus Appropriations legislation into law containing the provisions at issue here. The section also defined the scope of protected activity by providing several exceptions. Specifically, the amendment provides in part:

> With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.[93]

"Medical activity" is defined as "the performance of a medical or surgical procedure on a body."[94] Medical activity does not, however, include: "[1] the use of a patented machine, manufacture, or composition of matter in violation of such patent, [2] the practice of a patented use of a composition of matter in violation of such patent, or [3] the practice of a process in violation of a biotechnology patent."[95] According to the conference committee summary, enforceable patented compositions of matter includes "novel uses of drugs, . . . chemical or biological reagents for diagnostic purposes, novel methods for scheduling or timing administration of drugs, . . . combining drug therapies, and . . . providing genetic or other biological materials to a patient (including gene therapies)."[96] The summary also explained that the validity of a hybrid claim[97] depends on whether the claim as a whole is exempted from enforcement in light of the medical activity definition.[98]

Like many other aspects of patent law, other countries view the patentability of medical procedures differently than the United States.[99] By

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93. 35 U.S.C. § 287(c)(1) (Supp. II 1996).

94. *Id.* § 287(c)(2)(A).

95. *Id.* §§ 287(c)(2)(A)(i)-(iii). The exception for "patented use of a composition of matter" does not include "a claim for a method of performing a medical or surgical procedure on a body that recites the use of a composition of matter where the use of that composition of matter does not directly contribute to achievement of the objective of the claimed method." *Id.* § 287(c)(2)(F). In other words, when the composition of matter does not play a major role in the invention, it is not patentable. The existence of a composition of matter does not convert an otherwise unenforceable patent for a medical procedure into an enforceable patent.

96. *Bill Signed, supra* note 79 (quoting conference committee summary).

97. In this context, a hybrid claim has at least one step that uses a composition of matter and at least one surgical step. *See id.*

98. *See id.*

99. An interesting question arises relative to patent infringement of a process patented in the United States when the goods are brought into the United States: Would a medical procedure patent

prohibiting enforcement of medical process patents, the United States has moved closer to the position of the majority of countries. For instance, Great Britain, the Commonwealth Nations, and the European Union consider medical procedures to be non-patentable subject matter.[100] Although the European Union is harmonizing their patent laws and are adopting this position by treaty, the United States is not required to prohibit medical procedure patents under recent trade agreements—which may lead to international political and legal quandaries.[101]

In sum, medical and surgical procedures are still patentable, but are not enforceable against medical practice practitioners unless the patent incorporates pharmaceuticals or medical devices.

IV. ANALYSIS OF THE CURRENT LAW

The patentability of medical procedures cannot be easily analyzed under one consideration. Rather, many principles must be considered and balanced. Such analysis encompasses the ethics of medical procedures, the effect the current laws have on the cost of medical care; unique legal considerations arising from the status of the current law, and the underlying philosophy and economics of patent law.

A. Ethical and Professional Considerations

The strongest argument for the recent patent law revision, and an argument that is easily understood by the non-legal community, is the effect

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be infringed if a patient traveled outside the U.S. to have a patented procedure done by a foreign medical practitioner and then reenters the U.S.? Who would be liable? Could the patient be stopped at the border? Under current law, products that are manufactured by an infringing process can be barred from entering the United States under 35 U.S.C. § 271(f). Section 271(f) provides in part:

> Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components *outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.*

35 U.S.C. § 271(f)(1) (1994) (emphasis added).

100. *See* 142 CONG. REC. H8276, H8277 (daily ed. July 24, 1996); *see also* Burch, *supra* note 6, at 1163-65; Beata Gocyk-Farber, *Patenting Medical Procedures: A Search For a Compromise Between Ethics and Economics*, 18 CARDOZO L. REV. 1527, Table II (1997); *see, e.g.*, European Patent Convention, Oct. 5, 1973, art. 52, cl. 4, 13 I.L.M. 268 (1974).

101. *See* 142 CONG REC. S11845, S11845 (daily ed. Sept. 30, 1996) (expressing concern that the revision violates obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and may establish precedent for other countries to discriminate against other types of technologies); 142 CONG REC. S11838, S11843-44 (daily ed. Sept. 30, 1996); *see generally* Robert W. Pritchard, *The Future Is Now—The Case for Patent Harmonization*, 20 N.C. J. INT'L L. & COM. REG. 291, 299-311 (1995).

that medical process patents would have on the sanctity of the medical profession and public policy in general.[102] The ethical and professional considerations are compelling, relevant, and material to resolving the debate over enforceability of medical procedure patents.[103] Forceful arguments are made regarding the potential restricted clinical and academic access to patented procedures.[104] Additionally, important issues arise when considering the physician-patient relationship, particularly with regard to the constitutional rights of privacy.[105] Also, when balancing the ethical norms, one must consider the quality and availability of care arguments and the possibility of patent suppression by their owners.[106]

The AMA argues that medical procedure patents may restrict clinical and academic access to necessary patented procedures. [107] For example, free dissemination of medical procedures is important to the mores of the profession and important[108] for continual innovation in the treatment of the

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102. The AMA, for example, raised several compelling ethical arguments when it condemned the patentability of medical procedure patents. *See generally* 1995 AMA Report, *supra* note 75, at 200-06. Since, several law review articles echoed these concerns. *See, e.g.*, Gocyk-Farber, *supra* note 100, at 1544-51; Katopis, *supra* note 6, at 352-56; Lara L. Douglas, Note, *Medical Process Patents: Can We Live Without Them? Should We?*, 3 J. INTELL. PROP. L. 161, 177-81 (1995).

103. The same ethical arguments against patenting of medical procedures can be raised against patenting medical devices—an accepted practice today. The AMA, however, expressly allows physicians to patent surgical or diagnostic instruments because "[t]he laws governing patents are based on the sound doctrine that one is entitled to protect one's discovery." AMERICAN MEDICAL ASSOCIATION, COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, CODE OF MEDICAL ETHICS § 9.09 (1994) [hereinafter AMA CODE OF MEDICAL ETHICS].

104. *See* 1995 AMA Report, *supra* note 75, at 201-05.

105. *See id.* at 204.

106. *See id.* at 202, 206. Specifically, the AMA Report states"

> [T]he patent[ed] process could influence a doctor's medical judgment as to the appropriate treatment. In cases in which a patented procedure would be the most advisable therapy, physicians might rationalize the performance of what could be an inferior procedure rather than become a licensee of the patent holder or refer the patient to a licensed physician.
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> ....
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> . . . "[T]he alternative to patenting is non-disclosure. . . . Without [the guarantee of some kind of reward for publicly disclosing the procedure through a patent,] those physicians who wish to protect their discoveries may keep them secret, thereby hindering the dissemination of knowledge."

Id. at 202, 205; *see also infra* notes 119-27 and accompanying text.

107. *See* 1995 AMA Report, *supra* note 75, at 202-04 ("The most compelling argument against the medical process patents is grounded in the unacceptable picture of a patented procedure becoming unavailable to patients who require it, particularly when no alternative exists. . . . [Further,] peer review serves as the primary regulatory mechanism for medical processes. Thus, the potential barriers to peer review from patenting could lead to a decrease in the quality and safety of new procedures."). Sharing of knowledge and skills "leads to the early evaluation of new technologies, and permits the rapid dissemination of improved techniques." AMA CODE OF MEDICAL ETHICS, *supra* note 103, § 9.08.

108. *See* 1995 AMA Report, *supra* note 75, at 202-05. In fact, the AMA reported that

sick and injured.[109] The common battle-cry pleads: What if the Heimlich maneuver or CPR were patented?[110] The demise of free dissemination, however, seems dubious to this Author for several reasons. First, it has not been proven, but rather merely argued, that free dissemination has waned since medical procedures have been allowed to be patented. Granted, there are many patents for medical procedures, but that is expected and indicative of the substantial dissemination precipitated by patents. A sudden change in conduct by medical practitioners seems doubtful. Second, patents offer a channel of dissemination that may not otherwise be available for many advances. There are a limited number of journals and symposiums available. Medical "inventors" may still prefer the notoriety of being published in *The Journal of the American Medial Association* or the *New England Journal of Medicine*, but only a few medical inventors receive such notoriety. Rather than hoarding medical secrets, inventors may disseminate them through patents. One problem often faced by medical inventors is that their innovation may not be "worthy" of attention by publications, but still be patentable. Third, many inventors may keep their discoveries secret in order to benefit financially. Thus, patents offer an additional avenue of dissemination, rather than a means of stifling the free flow of medical discoveries.

Another ethical argument against medical procedure patents is their harmful effect on the physician—patient relationship.[111] Although physician—patient concerns are not new,[112] they are particularly important because they go to one of the underlying premises of the Hippocratic Oath.[113] One concern is that a patient's right to privacy may be invaded by a patent holder during an infringement lawsuit. Patients may be less likely to fully disclose medical conditions if they know that their treatment is not absolutely

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"[s]ince the time of Hippocrates, physicians have relied on the open exchange of information without the expectation of financial reward for advancing medical science." *Id.* at 201.

109. *See id.* at 204-06. Furthermore, the AMA stated that "[i]t is senseless to fault patenting for restricting access to medical procedures if the procedures would not have been developed otherwise." *Id.* at 204.

110. *See, e.g., Medical Procedures Hearings*, *supra* note 70, at 56, 57, *reprinted in* 1995 WL 615751 (statement of Charles D. Kelman, M.D., American Society of Cataract and Refractive Surgery).

111. *See* 1995 AMA Report, *supra* note 75, at 204 ("[M]onitoring of medical procedures could potentially compromise the privacy of both patients and physicians.").

112. *See, e.g.*, Burch, *supra* note 6, at 1152-55; Gocyk-Farber, *supra* note 100, at 1544-52.

113. One form of the Hippocratic Oath provides in part: "I swear . . . that I will fulfil according to my ability and judgment this oath and this covenant . . . to teach . . . this art . . . without fee and covenant . . . ." Ludwig Edelstein, *The Hippocratic Oath: Text, Translation and Interpretation, in* LEGACIES IN ETHICS AND MEDICINE 14 (Chester R. Burns ed., 1977).

confidential. The truth, however, is that a patient's treatment is not absolutely privileged and may be divulged in other unrelated instances.[114]

Another physician-patient concern is that a patient's usual physician may not be able to provide the proper treatment because she is not licensed to practice a particular process.[115] Perhaps a patient that is in need of a certain medical treatment is unable to afford or locate the proper physician that is licensed to practice the necessary care. This argument, however, is contrary to how the health care industry operates. Today, in the world of massive health care providers, it is rare that people have absolute, or even any, choice regarding which physician they see. Such health-care providers already restrict treatment as well as physician choice. Thus, the possibility of a patent dictating which physician one sees is insignificant and subversive as compared with to the choice provided by the health-care provider in the first place.

Additionally, there is a concern as to the effect that enforceable medical patents could have on the medical care that a physician is willing to give her patient.[116] Physicians, undoubtedly aware of civil liability, may be reluctant to treat a patient who needs urgent care where the procedure consists of a patented procedure and the physician is not "licensed" to use it. This situation is unlikely because a court enforcing infringement remedies might not grant injunctions under existing equitable doctrines for emergency procedures.[117] Moreover, it is hard to accept that a physician would not provide emergency

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114. Such instances of destruction of the privilege may occur in compliance with government health care provisions, actions concerning health or life insurance fraud, and perhaps medical device or pharmaceutical patent infringement actions. *See* Burch, *supra* note 6, at 1154-55.

115. *See* 1995 AMA Report, *supra* note 75 at 202 ("[T]he patent process could influence a doctor's medical judgment as to the appropriate treatment. In cases in which a patented procedure would be the most advisable therapy, physicians might rationalize the performance of what could be an inferior procedure rather than become a licensee of the patent holder or refer the patient to a licensed physician.").

116. *See id.* at 202 ("[T]he patent process could influence a doctor's medical judgment as to the appropriate treatment. In cases in which a patented procedure would be the most advisable therapy, physicians might rationalize the performance of what could be an inferior procedure rather than become a licensee of the patent holder or refer the patient to a licensed physician.").

117. *See, e.g.*, Steven L. Nichols, Comment, *Hippocrates, the Patent-Holder: The Unenforceability of Medical Procedure Patents*, 5 GEO. MASON L. REV. 227, 260-61 (1997) (suggesting that the tort remedy of the doctrine of necessity could protect medical practitioners who used a patented medical procedure in an emergency situation). In this situation, public policy justification, such as the "doctrine of necessity," might be argued to overcome the patent owner's rights. *Cf.* Vincent v. Lake Erie Transp. Co., 124 N.W. 221 (Minn. 1910); Ploof v. Putnam, 71 A. 188 (Vt. 1908). Such a justification, however, does not necessarily address the compelling ethical arguments or balance the policies, and probably would not be sufficient to pacify the anti-patent crowd. Further, it serves more of a litigation excuse or defense and does not serve the doctors facing the possibility of a patent infringement suit.

care because of patent concerns. Injunctions require consideration of, *inter alia*, the impact if any, on the public interest.[118] Clearly, the public interest and the health of an individual outweigh the patentee's need to enforce the patent. In such a case, a compulsive license gives society the health care needed and gives the patentee just compensation for the use of the patent.

Another concern relating to all patents is patent suppression.[119] Patent suppression occurs when a patentee refuses to allow another to use or license his or her own invention.[120] Although patent suppression may conflict with Constitutional objectives,[121] there is no general duty to use or allow others to use a patent.[122] The proponents of the legislation may argue that patent suppression will result if medical procedure patents are enforceable and a patentee wishes to strictly enforce his patent. This conduct, however, is unlikely, particularly in the medical community where many physicians turn to patents as a source of recognition of their accomplishments, instead of turning to medical journals or periodicals.[123] Despite the fact that medical process patents have been issued for almost forty-six years, actual cases of patent suppression are uncommon and unknown to medical procedure patents, except for instances where an inventor is attempting to dominate a particular market. The fact that only one case has been brought for patent infringement is testimony of the unlikelihood of patent suppression occurring.[124] Further,

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118. *See* Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 219 U.S.P.Q. (BNA) 686 (Fed. Cir. 1983). The four factors that must be considered when deciding whether to grant an injunction are (1) whether the movant has sufficiently established a reasonable likelihood of success on the merits; (2) whether the movant would suffer immediate irreparable harm if the injunction were not granted; (3) what impact the injunction will have, if any, on the public interest and (4) whether the balance of hardships tips in the movant's favor. *See id.* at 1578-79.

119. *See* Jeremy Waldron, *From Authors to Copiers: Individual Rights and Social Values in Intellectual Property*, 68 CHI.-KENT L. REV. 841, 866 (1993); 1995 AMA Report, *supra* note 75, at 202, 205.

120. *See, e.g.*, PRINCIPLES OF PATENT LAW *supra* note 14, at 44-45.

121. *See* Vitamin Tech. Ind. v. Wisconsin Alumni Research Found., 146 F.2d 941, 65 U.S.P.Q. (BNA) 285 (9th Cir. 1944).

122. *See* Special Equip. v. Coe, 324 U.S. 370, 64 U.S.P.Q. (BNA) 525 (1945); Continental Paper Bag Co. v. Eastern Paper Bag Co., 210 U.S. 405 (1908). Patent suppression may be attacked on antitrust grounds. A unilateral refusal to license a patent may be challenged as a monopolization or attempts to monopolize under section 2 of the Sherman Act. *See* 15 U.S.C. § 2 (1994).

123. *See Medical Procedures Hearings*, *supra* note 70, at 38-39, 40, *reprinted in* 1995 WL 615761 (statements and testimonies of Samuel L. Pallin, M.D., F.A.C.S.); Felsenthal, *supra* note 70, at B1 ("Most physicians who hold so-called method patents appear to be more interested in licensing their techniques than restricting access."). Before filing for a patent, Dr. Pallin submitted an article to the *Journal of Cataract & Refractive Surgery*, but received a "tersely worded rejection letter that, among other things, dubbed his research of 'very little importance.'" Ron Stodghill II, *Should Surgical Techniques Be Given Protection?*, BUS. WK., July 24, 1995, at 86.

124. The lawsuit brought by Dr. Pallin against Dr. Singer is regarded as the first suit to enforce a medical procedure patent.

the patentee would not decline licensing the procedures and could not receive injunctive relief, rather only monetary relief. The patentee is unlikely to recover injunctive relief because the public interest to promote health heavily outweighs the private interest.[125] Additionally, the disclosure of a medical patent is, arguably, better than what is available by publication in medical journals.[126] In sum, patent suppression would be unlikely.[127]

B. The Effect of Enforcement on Health Care Costs

Another argument against enforcement of medical process patents is that it would drive-up health-care costs to the point where people will be unable to afford the monopoly prices of medical treatment.[128] Since the 1960s, the health-care system has been dominated by rapidly escalating health care costs and "the increased involvement of Wall Street-listed corporations providing

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125. *See* PRINCIPLES OF PATENT LAW, *supra* note 14, at 1351-52 (construing City of Milwaukee v. Activated Sludge, Inc., 69 F.2d 577 (7th Cir. 1934)).

126. The rationale for this contention is simply that for a patent application to issue, the invention must, *inter alia*, be useful, novel, and nonobvious, and the application must set forth a written description of the invention, disclose the best mode of carrying out the claimed invention, and "enable any person skilled in the art" to make and use the invention. *See* 35 U.S.C. §§ 101, 103, 112 (1994). In comparison, medical journals have their own requirements for publishing, for example, the Journal of the American Medical Association (JAMA) is peer reviewed and recites criteria for manuscript acceptance. *See JAMA Instructions for Authors, Manuscript Criteria and Information* (visited Feb. 7 1999) <http://www.ama-assn.org/public/journals/jama/instruct.htm>. Specifically, JAMA provides that

> Manuscripts should meet the following criteria: the material is original; the writing is clear; the study methods are appropriate; the data are valid; the conclusions are reasonable and supported by the data; the information is important; and the topic has general medical interest. From these basic criteria, we assess a paper's eligibility for publication. We receive approximately 4300 papers each year, but publish only about 11% of unsolicited manuscripts.

Id. Although publication in medical journals have rigorous standards, which are not completely unlike the requirements of patentability, does not, of course, have a Constitutional basis and is not a function of statutes and regulations, which are, for the most part, rigidly administered by a federal agency and federal courts.

127. Indeed, patent suppression would be moot if there was compulsive licensing. *See infra*, Section IV.D. A related concern is that without patent protection, medical procedures may be treated as trade secrets by inventors that wish to capitalize on their investment and research. Although protection under trade secret law is dubious, the effect of the inventors treating their invention as such by not publishing advances in journals or disclosing them in patents, contravenes patent law policy and stymies dissemination of information. In other words, such effect is contrary to the theoretical underpinnings of patent law: betterment of society from the disclosure and improvement on the prior art.

128. *See* 140 CONG. REC. E1754, E1754 (daily ed. Aug 17, 1994) (extension of remarks of Representative John Bryant); 1995 AMA Report, *supra* note 75, at 204 ("[P]atenting of medical procedures may lead to an increase in the cost of health care via licensing fees or the costs of infringement litigation.").

primary services and health care."[129] Furthermore, these rapidly increasing health-care costs have out-paced inflation.[130] This rapid increase "had many causes," including general inflation,[131] greater scientific and technological sophistication,[132] demographic factors,[133] and a surplus of health care providers.[134] Recently, however, health care costs have enjoyed flat inflation in recent years.[135] This has not stopped the proponents of the legislation from alleging that enforcement of medical process patents will drive up health care costs.[136]

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129. STANLEY WOHL, M.D., THE MEDICAL INDUSTRIAL COMPLEX 17 (1984).

130. ANNE M. STOLINE, M.D., & JONATHAN P. WEINER, PH.D., THE NEW MEDICAL MARKETPLACE: A PHYSICIAN'S GUIDE TO THE HEALTH CARE SYSTEM IN THE 1990S 34 & Figure 10 (1993). In 1960, health care expenditures were slightly greater than 5% of the Gross Domestic Product (GDP), but in 1991 they were 13% (or $738 billion). *Id.* at 34 Figure 10. Higher prices were the major cause of increased expenditures from the mid-1970s through the late 1980s. *See id.* at 35. Between 1965 and 1976, "[o]ver 50 percent of the [health care] increases resulted from higher prices . . . ." Stuard H. Altman & Stanley S. Wallack, *Is Medical Technology the Culprit Behind Rising Health Costs? The Cases for and Against, in* MEDICAL TECHNOLOGY: THE CULPRIT BEHIND HEALTH CARE COSTS? 24, 25 (Stuart H. Altman & Robert Blendon eds., 1977).

131. *See* STOLINE & WEINER, *supra* note 130, at 31. Although general inflation is a major factor, health care costs escalated more rapidly than the rest of the economy. *See id.*

132. *See id.* at 32 ("[Such sophistication] increased hospital prices significantly . . . because of the costs associated with purchasing equipment, training specialized employees, and maintaining complex machines."). The decreased costs and improved quality of life attributable to the technology mitigate this factor. *See id.*

There are two types of forces that drives up health care costs, external and internal. Charles A. Sanders, *Technology and the Hospital, in* MEDICAL TECHNOLOGY, *supra* note 130, at 59. External forces include (1) the public, believing that health care was a right and that the more resources devoted to health care the better; (2) the government, fulfilling the public's demand; (3) third-party private payers; (4) private industry and individual inventors; and (5) universities. *See id.* at 57-61. Internal forces mostly stem from individual physicians or specialty unit and partially from hospitals. *See id.* at 61-62.

133. *See* STOLINE & WEINER, *supra* note 130, at 32 ("Not only has the U.S. population continued to grow, the average age of this population has been rising [as well]."). The aging population increases costs because they "have a higher incidence of chronic disease, [and] more tests, treatments, and hospital admissions." *Id.*

134. *See id.* at 33.

135. *See* Ron Winslow, *Health-Care Inflation Kept in Check Last Year*, WALL ST. J., Jan. 20, 1998, at B1; David Wessel, *Health-Cost Trims Hold Inflation Down*, WALL ST. J., June 30, 1997, at A1. The flat inflation may be due in part to the migration to 85% membership in managed-care or health maintenance organizations (HMOs), and their "tight-fisted" management. *See* Winslow, *supra*, at B1. "Managed care is now the driving force of the emerging health care provisions in the United States." Robert B. King & Benn Moore III, *Managed Care Past, Present, and Future*, ARCHIVES OF NEUROLOGY, Sept. 1996. The inflation in health care costs may soon continue to rise without additional cost saving options. *See* Winslow, *supra*, at B1.

136. One commentator noted that although improvements in medical care often directly result from new technology advances, there is concern for the substantial cost of medical technology where there is not for other scientific research, training, and technological development. *See* Robert J. Blendon & Thomas W. Moloney, *Perspectives on the Growing Debate Over the Cost of Medical Technologies, in* MEDICAL TECHNOLOGY, *supra* note 130, at 10 ("In fact, [scientific and

Not surprisingly, this argument is not new. In 1902 and 1903, Congress contemplated allowing the patentability of medical procedures and devices, but legislation was never enacted[137] and the resulting effect on health care costs has been indiscernible.[138] Since then, many medical procedures and devices have been patented without any nexus between patents and health care costs being established.[139] Progress in medicine, however, is often attributed to driving health care inflation.[140] Although health care inflation may be a result of aggressive investment in expensive new treatments, which result from research and development in drugs, devices, and procedures, the resulting technology often ultimately realizes a net savings due to the effect of the inventions on shortened hospital stays, less intensive care treatment, and general efficiency. Also, many areas of health care have significant competition to keep costs down.[141] This rise in health care costs is cited to defeat the enforceability of medical procedures, but seems to be less relevant with regard to medical devices.

Also, this argument is unconvincing because it could be just as easily applied to medical devices but is not. In other words, a different standard is applied to medical devices and medical procedures. The different standard may be explained by the earlier acceptance of device patents and the substantial investment necessary for many medical devices. The historical and prolonged acceptance of the patentability of medical devices may make it more difficult to attack and displace. The rationale is best justified by the

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technological advancements have] been . . . major factor[s] in our continuous economic growth.").

137. *See generally* Noonan, *supra* note 63, at 657.

138. *See, e.g.*, Sanders, *supra* note 132, at 57 ("Despite enormous growth in technological fields, little quantitative information is available concerning technology's cost, impact on health, or mechanism of introduction.").

139. *But see* STOLINE & WEINER, *supra* note 130, at 32 ("Greater scientific and technologic sophistication, resulting in more complex services, . . . contributed to . . . price increases."); *but see, e.g.*, Felsenthal, *supra* note 70, at B1 ("[E]fforts to collect royalties could add to the nation's health-care tab. For one thing, disputes over the validity of particular patents could run up millions of dollars in legal fees. These expenses—and the cost of any royalties themselves—undoubtedly would be passed on to patients.").

140. *See* J.D. Kleinke, *Pricing Health Care: The Health Care Inflation Fantasy*, WALL ST. J., Oct. 18, 1993, at A16.

141. *See* Mary T. Griffin, *AIDS Drugs & the Pharmaceutical Industry: A Need for Reform*, 17 AM. J.L. & MED. 363, 370-71 (1991) ("The prospect of patents motivated manufacturers to develop new, therapeutically different drugs to displace existing therapies at higher prices. The relatively low cost of developing a drug and the high rates of return led to an increased emphasis on R & D in the search for new, patentable drugs."). For example, the antibiotic market "experiences the greatest price competition and has the lowest percentage of patent protected products." *Id.* at 371 n.36 (citing United States Dep't Of Health Educ. & Welfare Task Force On Prescription Drugs, *The Drug Makers And Drug Distributors*, 39 (1968)). To predict that the medical procedure market would not act like pharmaceuticals is a tenuous conviction.

greater investment typically needed for medical devices. The expensive invention, disclosure, and innovation of medical devices require protection for the investors. Without patent protection, the invention of medical devices may never occur if the inventors and investors cannot protect their investment. This justification should be bootstrapped onto medical procedures. Clearly, many inventive medical procedures today require significant time and financial investment. It becomes readily apparent that the double standard does not hold up when medical procedures require significant investment.[142] Without an investment-based rationale, the argument against enforcing medical procedure patents rests primarily on ethics.[143]

C. Legal Considerations

Several legal considerations arise in light of the recent legislation, including patent misuse, fraudulent conduct in connection with medical devices, and regulatory takings.

1. Patent Misuse

The enforceability of medical process patents, in conjunction with patented medical devices or other procedures, may give rise to patent misuse in the form of an unlawful tying arrangement. Patent misuse occurs where the patent owner "uses [the patent] in violation of the antitrust laws or uses it to expand the scope of the patent right with an anticompetitive effect."[144] "A tying arrangement is 'an agreement by a party to sell one product [the tying product] but only on the condition that the buyer also purchases a different (or tied) product, or at least agrees that he will not purchase that product from any other supplier."[145] The discrimination of medical procedures under the patent laws may encourage arrangements where a medical procedure could be tied to the use of a patented medical device or pharmaceutical. Such an arrangement

142. It is ironic that today's financially driven medical industry, dominated by mammoth health care providers like HMOs, raise ethical and altruistic notions of medicine and patient care against patent law. Medical care now focuses on providing maximum profit, yet shroud an attack on the patent law in the Hippocratic Oath.

143. Senator Hatch characterized the amendment as an "unprecedented change to our patent code," noting that it "is bad patent policy" and that "exempt[ing] large multi-million dollar organizations such as HMOs from the reach of patent code enforcement, flies in the face of the American tradition of encouraging individual initiative." 142 CONG. REC. S11838, S11843 (daily ed. Sept. 30, 1996).

144. HERBERT F. SCHWARTZ, PATENT LAW & PRACTICE 92 (2d ed. 1996).

145. Eastman Kodak Co. v. Image Technical Serv., Inc., 504 U.S. 451, 461 (1992) (quoting Northern Pac. R. Co. v. United States, 356 U.S. 1, 5-6 (1958)). A tying arrangement violates section 1 of the Sherman Act if the seller has "appreciable economic power." *Id.* The Sherman Act, as amended, is codified at 15 U.S.C. §§ 1-7. *See* 15 U.S.C. §§ 1-7 (1994).

may constitute an illegal tying arrangement and an attempt to extend the legal monopoly on the patented device to the medical procedure.[146] Antitrust laws prohibit such arrangements because they force consumers to purchase unwanted or unneeded services or products and, more importantly, drive up the overall cost to the consumer-patient. Finally, patent misuse may provide an affirmative defense to a charge of infringement.[147]

2. Fraudulent Use of the Medical Device Patent Exception

Technical improvements to medical instrumentation have had the most significant impact on health care in the last 100 years.[148] "Technological progress in medicine gives rise to newer and more effective equipment for diagnosis and treatment."[149] This is reflected in the amount of investment often required to make certain advancements.[150] Clearly, such an investment must provide the investors with a return on their investment, and patent monopolies provide such an opportunity.[151] If not, the money would go to other technologies that allow an exclusive right to exploit a patent and thus would leave society worse off without the betterment of the medical device. Even the AMA recognizes this argument and supports the issuance and enforcement of patents for medical devices.[152]

The AMA's incongruous position begs the question: How do medical devices differ from medical procedures?[153] Medical devices often perform the

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146. *See* International Salt Co. v. United States, 332 U.S. 392, 75 U.S.P.Q. (BNA) 184 (1947). A tying arrangement requires (1) distinct markets for the tying and tied product; (2) sufficient economic power in the tying product; and (3) the arrangement affects more than an insubstantial amount of commerce. *See Eastman Kodak*, 504 U.S., at 461-62.

147. *See* Maureen McGuirl, *Unilateral Refusals to License Intellectual Property, in* INTELLECTUAL PROPERTY ANTITRUST 1997, at 687 (PLI Pats., Copyrights, Trademarks, and Literary Prop. Course Handbook Series No. 483, 1997).

148. MODERN HIPPOCRATES, *supra* note 46, at 214.

149. LES SEPLAKI, COST AND COMPETITION IN AMERICAN MEDICINE: THEORY, POLICY AND INSTITUTIONS 153 (1994) ("However, the technological marvels of medicine are very expensive to purchase [and] maintain.").

150. As one can imagine, the amounts could range vastly.

151. *See* Rebecca Eisenberg, *Patents and the Progress of Science*, 56 U. CHI. L. REV. 1017, 1024-25 (1989).

152. The AMA expressly allows physicians to patent surgical or diagnostic instruments because "[t]he laws governing patents are based on the sound doctrine that one is entitled to protect one's discovery." AMA CODE OF MEDICAL ETHICS, *supra* note 103, § 9.09.

153. In a letter to the Editor, H. Dunbar Hoskins, Jr., M.D., the Executive Vice President of American Academy of Ophthalmology, wrote:

> Patents on drugs and medical devices are different from patents on medical . . . procedures. Patents on drugs and medical devices serve a necessary purpose: providing incentives for innovation and encouraging the investment required for the research, development and marketing of inventions. Patents on medical . . . procedures serve no purpose other than to

same function as medical procedures, but in a different way.[154] Medical devices perform the same function that medical practitioners do, including testing, diagnosing, and even repairing body parts, albeit in an automated or electro-mechanical way.[155] Arguably, medical devices perform medical procedures more efficiently than if a physician performed the same procedure manually.[156]

A "loop-hole"[157] was created in the revised statute to permit enforcement of patents that involve a procedure when it is performed in conjunction with a patented medical device.[158] The loophole may encourage inefficient efforts and attempts to circumvent the new law. For instance, physicians may purposefully design or patent a medical device to bring their medical procedure within the § 287(c) exception. Such conduct is costly, inefficient, and harmful to society. Even Dr. Pallin remarked that if he had created a device to go along with the procedure, he would have an enforceable patent today.[159]

3. Regulatory Takings

The recent regulation may constitute a Fifth Amendment taking of a property right on the grounds that the inventor's property, which is still awarded a patent, is rendered worthless because the inventor/patentee has no right to exclude.[160] The Fifth Amendment provides that "private property [shall not] be taken for pubic use, without just compensation."[161]

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enrich the person or organization that holds the patent.
Hoskins, *supra* note 76.

154. *See* MODERN HIPPOCRATES, *supra* note 46, at 214 ("The new technologies had the capacity themselves to sense evidence and, most critically, to transform it into the objective forms of pictorial, graphic, or numerical data.").

155. *See generally id.* at 214-15.

156. *See id.* at 215-16. For a time, developments of medical technology splintered medical professionals and scholars into those that accepted the benefits of technology for its exactness and precision and those that relied on clinical diagnoses and thought physicians were becoming mechanics. *See id.* at 215.

157. 142 CONG. REC. S11845, S11845 (daily ed. Sept. 30, 1996) (summary of statement of PTO Comm. Lehman).

158. "Performance of a [patented] medical or surgical procedure on a body" constitutes infringement, except where "the use of a patented machine, manufacture, or composition of matter in violation of such patent." 35 U.S.C. § 287(c)(2)(A) (Supp. II 1996).

159. *See Medical Procedures Hearings*, *supra* note 70, at 40-42, *reprinted in* 1995 WL 615761 (statements and testimonies of Samuel L. Pallin, M.D., F.A.C.S.).

160. A "taking" refers to the government's implicit right of eminent domain under the Fifth Amendment. *See* BLACK'S LAW DICTIONARY 1454 (6th ed. 1990) ("[T]he act of laying hold upon an article, with or without removing the same. [A taking] implies a transfer of possession, dominion, or control."). Specifically, the Fifth Amendment provides that private property shall not "be taken for public use, without just compensation." U.S. CONST. amend. V. When considering whether a

To constitute a regulatory taking, government foreclosure of a particular use is not enough, rather, all economically viable use must be taken.[162] "Several factors... should be taken into account [in an ad hoc, factual inquiry] when determining whether a governmental action has gone beyond 'regulation' and effects a 'taking.'"[163] These factors include "the character of the governmental action, the economic impact of the regulation, and its interference with reasonable investment-backed expectations."[164] One way that a taking may occur is by government regulation that renders property worthless. The government may regulate property use in a manner consistent with its "police power" without compensation even though the owner's use of the property or the property's value has been substantially diminished.[165] However, "[t]he general rule at least is that while property may be regulated to a certain extent, if regulation goes too far it will be recognized as a taking."[166] Generally, a regulation that denies all economically beneficial use of land will be a taking and must be compensated.[167]

Case law indicates that the Takings Clause applies to intellectual property, particularly patents.[168] Cases in recent years indicate that another form of

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taking has occurred, a court considers the extent that the government has interfered with expectation from investment. *See* Penn Cent. Transp. Co. v. New York City, 438 U.S. 104, 123-24 (1978). Investment in technology, such as medical devices and procedures, have certain return on investments, the same as other industries.

161. U.S. CONST. amend. V.

162. *See* Lucas v. South Carolina Coastal Council, 505 U.S. 1003, 1016 n.6 (1992) ("The cases say, repeatedly and unmistakably, that '[t]he test to be applied in considering [a] facial [takings] challenge is fairly straightforward. A statute regulating the uses that can be made of property effects a taking if it denies an owner economically viable use of his land.'"); *see also* Keystone Bituminous Coal Ass'n v. DeBenedictis, 480 U.S. 470, 495 (1987); Hodel v. Virginia Surface Mining & Reclamation Ass'n, 452 U.S. 264, 295-96 (1981).

163. Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1005 (1984).

164. *See* Kenneth L. Port, *The "Unnatural" Expansion of Trademark Rights: Is a Federal Dilution Statute Necessary?*, 18 SETON HALL LEGIS. J. 433, 468 (1994) (discussing trademark protection under dilution theories) (citing *Ruckelshaus*, 467 U.S. at 1005; *Kaiser Aetna*, 444 U.S. at 175; *Penn Cent.*, 438 U.S. at 124).

165. *Lucas*, 505 U.S. at 1022-23. Fifth Amendment takings generally arise in the regulation context of zoning, environment protection, or landmark preservation. Generally, for a land-use regulation to avoid being a taking, it must "substantially advance legitimate state interests" and must not "deny an owner economically viable use of his land." Agins v. Tiburon, 447 U.S. 255, 260 (1980). The legitimate purpose requires that there is a relatively tight fit between the means chosen by the state and the governmental objective being pursued. *See* Nollan v. California Coastal Comm'n, 483 U.S. 825 (1987).

166. Pennsylvania Coal Co. v. Mahon, 260 U.S. 393, 415 (1922).

167. *See Lucas*, 505 U.S. at 1015.

168. *See* James v. Campbell, 104 U.S. 356, 358 (1881) ("[A patented invention] cannot be appropriated or used by the government..., without just compensation, any more than it can appropriate or use without compensation land which has been patented to a private purchaser, we have no doubt.").

intellectual property, trade secrets, may be protected under the Fifth Amendment from a regulatory taking, but none thus far have been raised regarding regulation of patent rights.[169] The position of inventors of medical processes is similar to those of inventors or companies in the trade secret cases. At great expense, companies have developed technology and must disclose information to governmental agencies according to regulations. If the government publishes the secret information, the companies would lose their competitive advantage. In the case of medical procedures, the inventor has made a substantial investment in developing the procedure. If the inventor is prohibited from enforcing her patent rights, there is no competitive advantage realized and there is no *quid pro quo* afforded to the inventor-investor. On the grounds that patent owner's holding medical procedure patents have had their property rendered worthless due to the recent legislation, this should constitute regulatory takings.

For example, in *Ruckelshaus v. Monsanto Co.*, the Supreme Court recognized that an intellectual property right might be afforded Fifth Amendment takings protection.[170] The controversy centered on the government's requirement that Monsanto submit health, safety, and environmental data, which contained trade secrets for a new pesticide, to the EPA.[171] Since 1972, applicants could signify information as trade secrets, which prohibited the EPA from publicly disclosing them.[172] In 1978, however, Congress amended the pertinent statutory provisions and allowed the EPA to disclose trade secrets (except manufacturing or quality control processes), but provided the applicant with a ten-year exclusive use period.[173] Because takings is an equitable doctrine, several factors are considered and balanced by the tribunal. Specifically, a court will inquire into (1) whether there is a recognized property interest; (2) whether there is a taking; (3) whether the taking was for public use; and (4) whether the statute provides for just compensation.[174] Further, a taking requires considering whether the government action (a) furthers a legitimate government interest; (b)

169. *See, e.g., Ruckelshaus*, 467 U.S. 986; Corn Prods. Refining Co. v. Eddy, 249 U.S. 427 (1919); United Steelworkers of Am. v. Auchter, 763 F.2d 728 (3d Cir. 1985); Northglenn v. Grynberg, 846 P.2d 175 (Colo. 1993).

170. *See Ruckelshaus*, 467 U.S. at 1003-04 (holding that a "taking" of trade secrets could be a violation of the Fifth Amendment). The court admitted that they have "generally been unable to develop any 'set formula' for determining when 'justice and fairness' require that economic injuries caused by public action must be deemed a compensable taking." *Id.* (quoting *Kaiser Aetna*, 444 U.S. at 175 (quoting *Penn Cent.*, 438 U.S. at 124 (1978))); *see also Hodel*, 452 U.S. at 295.

171. *See Ruckelshaus*, 467 U.S. at 995-96.

172. *See id. at* 992.

173. *See id. at* 994.

174. *See id.* at 1000-01.

effectively deprives the property owner of all economic value; and (c) interferes with investment expectations.[175]

By precluding patent owners from enforcing their patent rights, 35 U.S.C. § 287(c) denies owners of all economic viable use of their property. The economic value of a patent property right lies in the competitive advantage that the patent laws provide. First, patent rights are a recognized property interest.[176] Second, the recent revision of the patent laws is a taking. Because a patent retains its value only so long as it can be enforced, the patentee has effectively lost all economic value of his property right. Further, the patentee had a reasonable investment-backed expectation that his patent rights would be enforceable against infringers. Third, the taking was for public use because it is rationally related to a legitimate government interest.[177] Finally, the patent owners of medical procedure patents have not received just compensation. Indeed, Congress has taken away any ability of a patentee to obtain a remedy for patent infringement. The patentee has suffered a loss because any medical practitioner may use the patented invention without just compensation.

D. PHILOSOPHY AND ECONOMICS OF PATENT LAW[178]

As our patent laws have developed, there has been considerable philosophical discussion attempting to explain, limit, or expand the law.[179] It

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175. *See* Agins v. City of Tiburon, 447 U.S. 255, 260 (1980); *Pennsylvania Cent.*, 438 U.S. at 123; *Ruckelshaus*, 467 U.S. at 1005.

176. *See* 35 U.S.C. § 261 (1994); PRINCIPLES OF PATENT LAW, *supra* note 14, at 5-6 & n.17. The Federal Circuit addressed both forms when it stated that "[s]ince property rights in an invention itself could not, under any conventional meaning of the term, be considered real property, they are by definition personal property." Filmtec Corp. v. Allied-Signal, Inc., 939 F.2d 1568, 1572, 19 U.S.P.Q.2d (BNA) 1508, 1511 (Fed. Cir. 1991). However, the court later stated that

> [u]nlike personal property, it cannot be lost or found; it is not liable to casualty or destruction; it cannot pass by manual delivery. Like real property, it may be disposed of, territorially, by metes or bounds; it has its system of conveyancing by deed and registration; estates may be created in it, such as for years and in remainder; and the statutory action for infringement bears a much closer relation to an action of trespass than to an action in trover an replevin. It has, too, what the law of real property has, a system of user by license.

Id. at 1572 n.5, 19 U.S.P.Q.2d (BNA) at 1511 n.5 (quoting A.S. Solomons v. United States, 21 Ct. Cl. 479, 483 (1886), *aff'd*, 137 U.S. 342 (1890)). Whether patents are considered real or personal property, they are indeed private property and afforded rights under the Constitution.

177. *See Ruckelshaus*, 467 U.S. at 1014.

178. A complete analysis would include a comprehensive dissertation regarding the philosophy and economic incentives of patent law. Because no substantive analysis is better than an ephemeral analysis, a complete philosophical and economic analysis is beyond the scope of this Comment. However, because complete absence of this poignant side of the issue would seem deficient, following is a general introduction.

seems that whether one considers medical process patents enforceable or an affront to civilized society, justification can be found for one's position. In the instant case, the relevant theories include Lockean theory[180] and utilitarian

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179. Judge Giles S. Rich wrote that there are several policy reasons for patent law, but the granting of patents is basically an incentive system having diverse objectives:

> (1) to encourage innovation, the creation of new things and processes; (2) to induce inventors to make early public disclosures of their creations and discoveries; (3) most importantly probably, to encourage the investment of risk capital in the commercialization of inventions so that the public gets to enjoy the benefits thereof; and finally; (4) the inducement of "inventing around" the patents on successful inventions to bring even more improvements to the public—a "we can do it differently, or even better," sort of thing.

Judge Giles S. Rich, *Foreword* to PRINCIPLES OF PATENT LAW, *supra* note 14, at iii. The Supreme Court has likewise debated the implication of granting the right to exclude. *Compare* Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 154, 87 U.S.P.Q. (BNA) 303, 306 (1950) ("Every patent is the grant of a privilege of exacting tolls from the public."), *with* Automatic Radio Mfg. Co. v. Hazeltine Research, Inc. 339 U.S. 827, 837, 85 U.S.P.Q. (BNA) 378, 382 (1949) ("[T]he public interest in patents comes first, reward to the inventor second."), *overruled in part by* Lear, Inc. v. Adkins, 395 U.S. 653, 162 U.S.P.Q. (BNA) 1 (1969). Further, Learned Hand once stated:

> It would indeed be absurd to rank the invention [in the case at issue] as a great pioneer such as come only at rare intervals and are the work of genius. Indeed, it is precisely those that probably need no patents to call them forth; the stimulus of profit has little or no part in their production. The patent law is aimed at animating a lower order of imagination and skill than that; more, it is true, than the ordinary rub of competition automatically brings out from competent workmen in the art, but not the superlative skills—at least that has been its uniform avowed purpose. Perhaps the system is outworn, but while it stands, it stands clothed with its history like any other statute, and it seems to us that not to recognize so substantial an achievement as this [invention], would deny recognition where recognition most is helpful.

Dewey & Almy Chem. Co. v. Mimex Co., 124 F.2d 986, 990-91, 52 U.S.P.Q. (BNA) 138, 143 (2d Cir. 1942).

180. Lockean theory has several derivations, including natural rights, deontological theory, and value added theory. *See generally* PRINCIPLES OF PATENT LAW, *supra* note 14, at 34-45.

Lockean theory generally holds that the common is owned by everyone and by exerting labor on the common, the product of the labor becomes part of the laborer. *See* John Locke, *Second Treatise on Civil Government, in* TWO TREATISES OF GOVERNMENT § 26, at 286-87, §§ 27-51, at 287-302. (Peter Laslett ed., 1988) ("The Earth, and all that is therein, is given to Men for the Support and Comfort of their being. And though all the Fruits it naturally produces, and Beasts it feeds, belong to Mankind in common, as they are produced by the spontaneous hand of Nature . . . ."). "*As much Land* as a Man Tills, Plants, Improves, Cultivates, and can use the Product of, so much is his *Property*." *Id.* § 32, at 290.

Deontologicalists consider the rights of the inventor as the sole focus of patent law, and the public welfare is immaterial. *See* PRINCIPLES OF PATENT LAW, *supra* note 14, at 34-35 & n.2 (citing THE OXFORD COMPANION TO PHILOSOPHY 154 (Ted Honderich ed., 1995) [hereinafter OXFORD COMPANION]); *see also* THOMAS MAUTNER, A DICTIONARY OF PHILOSOPHY 99-100 (1996) ("Moral theories according to which the rightness or obligatoriness of an action is not exclusively determined by the value of the consequences, but where other considerations can also be relevant . . . . Consequently, a deontological ethical theory may properly be called non-utilitarian, or non-consequentialist.").

Under these ideological standards, inventors of medical process patents are valid and the inventors should be afforded all rights of other patent owners—even the right to exclude. When one

theory.[181]

Besides philosophical justifications, there are several economic theories that justify the United States patent laws.[182] Economic incentives constitute

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solely focuses on the rights of the inventor, many of the anti-enforcement arguments are irrelevant. Under Lockean theory, by creating a medical procedure, whether by thought or practice or both, the invention becomes the inventor's property. Medical procedure patents are created through labor of an individual or a team. Certainly, medical procedure inventions may involve specific efforts that result in social value.

181. Utilitarianism (or consequentialism) is a teleological theory that looks to the benefit to society for justification of an incentive based patent law. *See* PRINCIPLES OF PATENT LAW, *supra* note 14, at 34-35 & n.1 (citing OXFORD COMPANION, *supra* note 180, at 154), 45-47; *see also* MAUTNER, *supra* note 180, at 81 ("[The many varieties of consequentialism theory] all have in common . . . that *consequences alone should be taken into account when making judgements about right or wrong.*").

Consequentialists would strongly consider the relative benefit to society in determining whether medical patents are enforceable by their owners. Here, the proponents to the recent legislation could argue that the benefit to society is questionable given the power of patent rights, assuming that the benefit of a medical procedure could be withheld from a person needing it. On the other hand, the fundamental *quid pro quo* is premised on the fact that many, if not all, inventors require incentive to invest time and capital into their inventions. *See, e.g.*, Fowle v. Park, 131 U.S. 88, 97 (1889) ("The policy of [patent] law is to encourage useful discoveries by securing their fruits to those who make them."); Special Equip. Co. v. Coe, 324 U.S. 370, 382, 64 U.S.P.Q. (BNA) 525, 531 (1945) ("The public purpose is 'to promote the progress of science and useful art.' The exclusive right of the inventor is but the means to that end."); *see also* Felsenthal, *supra* note 70 (reporting that James Longacre, Dr. Pallin's attorney, stated that patents "encourage[] people to sit down with a glass of scotch and think up new ideas.").

182. Generally, discussion of the various economic incentives generally separate "incentive" into the incentive to invent, disclose, and innovate. *See generally* Eisenberg, *supra* note 151.

The incentive to *invent* theory provides that the investment necessary for invention would be unavailable but for patent protection. *See id.* at 1024-28. On the one hand, one may argue that medical procedures do not require significant investment as compared to other inventions; therefore, the economic incentive to invent is absent. Further, proponents may argue that "inventors" of medical procedures do not require incentives for their creations, as evidenced by the fact that medical procedures patents are rare, and by the absence of enforcement proceedings against infringers of medical procedure patents. On the other hand, others may argue that investment is crucial and expectations of return on investment are what drive venture capital investment in the first place. Without government funded research, venture capital is vital.

The incentive to *disclose* theory holds that "in the absence of patent protection, investors would keep their inventions secret in order to prevent competitors from exploiting them." *Id.* at 1028. "Secrecy prevents the public from gaining the full benefit of new knowledge and leads to wasteful duplicative research" and does not necessarily protect the product from would-be infringers reverse engineering the invention. *See id.* On the one hand, one may argue that free riders are not considered a problem in the medical community because new procedures have historically been freely disseminated throughout the medical community, and there is not a need to force disclosure because of the wide dissemination of information and the pursuit of recognition. On the other hand, the opposite, however, may just as likely be true, particularly where there is considerable investment in a new procedure and a reward for secrecy or nondisclosure. Often, inventors have an incentive to keep their discoveries private in order to reap the financial benefits of being the only provider of the inventive medical procedure. The same may occur with patents, but society would enjoy the benefits of complete disclosure and enablement. Admittedly, free dissemination may occur with simple or marginal advances, but is difficult and unreliable for significant inventions due to the inherent

one-half of the *quid pro quo* between the government and the inventor. In a perfect world, inventors would not need incentives to invent, and inventions would not need to be protected from piracy. Research and development of medical procedures, however, often require a substantial investment.[183] Moreover, even the AMA admits that *some* medical technologies require extensive research and development and "might not have been available at all in the absence of the patent system."[184]

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complexity and limited number of channels of information.

The incentive to *innovate* theory is commonly split into two distinct camps, the Schumperterian theory and the Prospect theory. Generally, innovation is the process of converting inventions to practical use so that society can enjoy it. Once an invention is realized, oftentimes there must be additional investment in order to make it useable by society in general. One camp, the Schumpeterians, believe that a patent monopoly is necessary to induce the transformation of invention to practical use and "stress[ing] the element of invention as much as writers do" is "not advisable, and... may be downright misleading." JOSEPH A. SCHUMPETER, THE THEORY OF ECONOMIC DEVELOPMENT: AN INQUIRY INTO PROFITS, CAPITAL, CREDIT, INTEREST, AND THE BUSINESS CYCLE 89 (Redvers Opie trans., Galaxy Book 1961) (1934) ("[Innovation is such an important component that inventions that] are not carried into practice... are economically irrelevant."); *see also* Eisenberg, *supra* note 151, at 1038-40.

183. Generally, inventors attain financing from the National Institute of Health (NIH) or similar government agencies, or from private venture capital. Private venture capital, as the name suggests, involves one or more persons investing money in research and development with the expectation that the investment will earn high rates of return if successful. In other technological fields, where patent protection is available, the possibility of a patent issuing and of the patented invention succeeding act as an assurance that venture capitalists will receive a return on their investment.

An common example of a medical procedure that may not have been discovered is the Surrogate Embryo Transfer (SET) technology. *See* 1995 AMA Report, *supra* note 75, at 204-05; *see also* Burch, *supra* note 6, at 1139-40; Noonan, *supra* note 63, at 656-57. The inventor sought funding through the NIH for researching embryo transfer procedures. *See* Noonan, *supra* note 63, at 656-57. The NIH, however, refused to fund the inventor who then turned to venture capital, which was attained only because of the invention's patentability. *See* Noonan, *supra* note 63, at 657. "[I]t is a questionable generalization to condemn all therapeutic procedure patents merely because the scleral frown incision patent does not appear to justify the public burden of a patent." *Id.* (commenting on the condemnation resulting from *Pallin v. Singer*).

Similarly, many medical devices are invented with minimal investment. Despite this enigma, medical procedure patents are not enforceable and non-medical procedure patents are enforceable. *See* 35 U.S.C. § 287(c) (Supp. II 1996). This paradoxical legal protection afforded to medical advances is perplexing and begs the question: why?

184. 1995 AMA Report, *supra* note 75, at 204.

V. THE FUTURE OF § 287(C) AND MEDICAL PROCEDURE PATENTS

A. The Current Standard of Patentability Is to Safeguard Medical Procedure Ethical Concerns

Patentability requirements[185] rigidly applied when determining the patentability of medical devices are sufficient safeguards for ethical transgressions and societal burdens. Like other inventions, in order for a medical procedure to be patented it must be useful, novel, nonobvious, and not prohibited by statutory bars. Such a standard is sufficient to patent a wide variety of inventions, including processes,[186] genetically engineered microorganisms,[187] and medical devices.[188] If the patent law, courts, and the PTO are capable of dealing with the complex issues of other complex patentable processes and biological subject matter, the justifications behind the non-enforceability of medical processes are dubious. Medical processes are as much or more susceptible to the safeguards imposed by nonobviousness and statutory bars.

Nonobviousness requires that "the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[189] Generally, medical procedures are, by their very nature, an incremental advancement over prior art.[190] This characteristic makes medical procedure applications susceptible to

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185. "[P]atentability is dependent upon three explicit conditions: novelty and utility as articulated and defined in § 101 and § 102, and nonobviousness . . . as set out in §103." Graham v. John Deere Co., 383 U.S. 1, 12, 148 U.S.P.Q. (BNA) 459, 464-65 (1966); *see also supra* notes 17-34 and accompanying text.

186. 35 U.S.C. § 101 (1994).

187. *See* Diamond v. Chakrabarty, 447 U.S. 303, 206 U.S.P.Q. (BNA) 193 (1980).

188. *See* 35 U.S.C. § 287(c) (Supp. II 1996).

189. 35 U.S.C. § 103 (1994).

190. A new combination of old ingredients is patentable, but mere substitution of an old ingredient with another ingredient that performs the same function infringes the patent. *See* Imhaeuser v. Buerk, 101 U.S. 647, 656 (1879). In fact, virtually all inventions, and hence all patent claims, are a combination of previously known parts. *See* MAC Corp. of Am. v. Williams Patent Crusher & Pulverizer Co., 767 F.2d 882, 884 n.3, 226 U.S.P.Q. (BNA) 515, 517 n.3 (Fed. Cir. 1985) ("Virtually all inventions are combinations of old, known elements"); Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1540, 218 U.S.P.Q. (BNA) 871, 880 (Fed. Cir. 1983) (citation omitted) ("Virtually *all* patents are 'combination patents,' if by that label one intends to describe patents having claims to inventions formed of a combination of elements."). Even before the current Patent Act, Judge Learned Hand noted the simple truism that everything new is in some sense a combination of old elements. *See* Safety Car Heating & Lighting Co. v. General Elec. Co., 155 F.2d 937, 939, 69 U.S.P.Q. (BNA) 401, 401 (2d Cir. 1946). Furthermore, Sir Isaac Newton may have considered himself not alone in his discoveries when he noted that "[i]f I have seen further (than you and Descartes) it is by standing on the shoulders of giants." Letter from Isaac Newton to Robert

attacks on nonobviousness. Rarely does a new procedure completely "reinvent the wheel." Thus, pertinent prior art and a "suggestion" may be found in the vast field of medical processes. The problem arises due to the PTO's inability to perform comprehensive prior art searches.[191] Although such invalidating prior art may be beyond that which is generally available to the PTO during prosecution, there are statutory devices available beyond expensive litigation to invalidate a patent.[192]

Additionally, loss-of-right provisions such as on-sale bar and public use provide relevant and adequate safeguards. Once the medical procedure is "ready for patenting," certain non-experimental activities begin the one-year deadline the inventor has to file for a patent.[193]

B. Reexamination Proceedings

Because of the nature of medical procedures, the PTO is ill prepared to search the relevant prior art to render a confidential determination of patentability. Further, the search at the PTO includes only a fraction of the pertinent prior art. Reexamination would allow third parties, with better access to prior art beyond patents, to present challenges to medical procedure patents.

Reexamination is an important procedure available to challenge the validity of a patent.[194] Reexamination occurs when the patent owner or a third party requests the PTO to reexamine a patent that has issued in light of relevant prior art that may not have been considered during prosecution. Patent owners sometimes request a reexamination in order to strengthen the validity of patents prior to or during infringement litigation. Likewise, third

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Hooke (February 5, 1675), *in* JOHN BARTLETT, FAMILIAR QUOTATIONS (Emily Morison Beck ed., 14th ed. 1968).

191. PTO prior art searches are generally limited to manual searches through "shoeboxes." Shoeboxes are boxes in which the PTO stores paper copies of patents. A more comprehensive search might use electronic searching, for example.

192. The primary method of challenging a patent when one does not have standing to bring a declaratory relief action is reexamination. The provision for reexamination is found in 35 U.S.C. §§ 301-307 (1994). *See* discussion *infra* Section V.B.

193. *See* Pfaff v. Wells Elecs., Inc., 119 S. Ct. 304, 311-12, 48 U.S.P.Q.2d (BNA) 1641, 1646-47 (1998) ("[T]he on-sale bar applies when two conditions are satisfied before the critical date. First, the product must be the subject of a commercial offer for sale.... Second, the invention must be ready for patenting. That condition may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention."). An issue that could arise is when a medical procedure is the subject of a commercial sale. Is there a commercial if a physician proposes a patented treatment? Is there a commercial sale if the patented treatment is performed during an emergency situation?

194. *See* 4 CHISUM ON PATENTS, *supra* note 47, at § 11.07.

parties may request a reexamination to narrow, weaken, or invalidate a patent.[195]

The patent laws provide that "[a]ny person at any time" may initiate a reexamination of a patent claim or claims by filing a request with the PTO.[196] The request must outline the relevance of each cited publication and be based on printed publications or patents.[197] The PTO grants a reexamination only if "a substantial new issue of patentability affecting any claim of the patent concerned is raised" the by the request.[198] Currently, only the patent owner may appeal an adverse decision.[199]

Even though the PTO is capable of doing a thorough search of prior patents, reexamination is effective because the PTO's access to other pertinent prior art is limited. Such pertinent prior art may be commonly known to only those in the field or only found in obscure publications. An expanded use of reexamination may weed-out questionable patents, narrow claims, and discourage weak applications.

C. The Imminent Eighteen Month Mandatory Disclosure Will Bolster Patent Validity

On August 16, 1994, the United States and Japan agreed to harmonize their patent systems, including requiring the publication of United States patent applications by the United States PTO after eighteen months from filing.[200] Such mandatory disclosure may allow interested parties or watchdog associations to submit relevant prior art references that the PTO could use to reject an application.

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195. There is no presumption of validity during a reexamination proceeding at the PTO. *See In re* Etter, 756 F.2d 852, 858, 225 U.S.P.Q. (BNA) 1, 5 (Fed. Cir. 1985) (en banc). Thus, reexamination proceedings may be attractive to defendants or third parties seeking to challenge the validity of a claim or claims. If a third party requests a reexamination, the patent owner may file a statement or amendment in response to the request, but such a filing gives the challenger an opportunity to reply to the patent owner's statement or amendment. Otherwise, a third party is not involved in the proceeding. *See* 35 U.S.C. §§ 304-305.

196. *See* 35 U.S.C. § 301. The reexamination statute provides, in part: "The request must be in writing . . . [and] set forth the pertinency and manner of applying cited prior art to every claim for which reexamination is requested." *Id.* § 302.

197. *See id.* § 301; *see also* 37 C.F.R. § 1.552 (1997).

198. *See* 35 U.S.C. § 304.

199. Recently, there has been legislation proposed that would allow a third party requester to appeal an adverse ruling or be a party to an appeal by the patent owner. *See* S. 507, 105th Cong. § 503(e) (1997).

200. *See generally* HAROLD C. WEGNER, PATENT HARMONIZATION 263-66 (1997); Symposium, *Early Patent Publication: A Boon or Bane? A Discussion on the Legal And Economic Effects of Publishing Patent Applications After Eighteen Months of Filing*, 16 CARDOZO ARTS AND ENT. L.J. 601 (1998).

Currently, a United States patent is not disclosed to the public until after issuance.[201] In many other countries, however, patent applications are published after a certain period of time following the filing of the application, oftentimes eighteen months.[202] Similar to options available to third parties during reexaminations, third parties could be allowed to submit documentary evidence to the PTO to be considered *during prosecution.* These submittals may be prior printed publications from anywhere in the world, or prior knowledge, use, or sale information in the United States.

Moreover, a mandatory disclosure of medical process patent applications would provide greater certainty to the validity of patents and discourage the application of procedures that are relatively simple, that are borderline obvious, or that require insubstantial investment. Although a mandatory disclosure would, at present, be an anomaly in the patent code and may not pacify some of the ethical arguments against enforcement, disclosure in an official gazette would provide the medical industry a voice during the prosecution of an application. Accordingly, medical procedures that have a strong case for patentability or require substantial investment, thereby needing protection to attain venture capital, could still be patented and enjoy the benefit of patent rights.

D. Sui Generis Solutions

Some commentators suggest a *sui generis* solution to rectify the perceived problem of medical process patents. For example, some suggest that medical procedure patents should also require compulsory licensing:

> [A] compulsory licensing provision that would require an owner of a therapeutic or diagnostic procedure patent to license the technology at a reasonable royalty . . . would assure the medical availability of any important therapeutic advance, provide a modest reward to the inventor, . . . protect the occasional procedure that required a large

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201. 35 U.S.C. § 11.

202. Countries that publish applications eighteen months after filing include the European Patent Convention, United Kingdom, Japan, Republic of Korea, and China. *See* EUC, Patents Act of 1977, as last amended by the Copyright, Designs and Patents Act of 1988, part I, sect. 16 (United Kingdom), *reprinted in* 8 WORLD INTELLECTUAL PROPERTY ORGANIZATION, INDUSTRIAL PROPERTY LAWS AND TREATIES OF THE WORLD at text 2-001, p. 013 (1998) [hereinafter WIPO]; Patent Law, Law No. 121 of April 13, 1959, as last amended by Law No. 30 of 1990 ch. III*bis*, sect. 65*bis*, *reprinted in* 4 WIPO, *supra*, at text 2-001, p.18; Patent Law (No. 950 of Dec. 31, 1961, wholly amended by Law No. 4207 of Jan. 13, 1990) ch. III, sect. 64 (Republic of Korea), *reprinted in* 6 WIPO, *supra*, at text 2-001, p. 020; Patent Law of the People's Republic of China, adopted Mar. 12, 1984, amended, adopted Sept. 4, 1992 ch. IV, art. 34, *reprinted in* 2 WIPO, *supra*, at text 2-001, p. 002; *see generally* Christopher R. Balzan, *Mandatory Publication of Patent Applications Prior to Issuance of Patents: A Desirable Change in U.S. Policy?*, 18 LOY. L.A. INT'L & COMP. L.J. 143 (1995).

> amount of venture capital to develop[, and] help alert potential patent applicants to the many legal and financial impediments presented by such patents . . . .[203]

Unlawful monopolization is sometimes remedied by compulsory licensing.[204] Congress has promulgated compulsory licensing statutes in other areas, including nuclear energy,[205] air pollution,[206] and plants.[207] Although exerting patent rights does not violate antitrust laws under Section 2 of the Sherman Act,[208] monopolization of a certain field by acquiring all available patents may be found to be unlawful.[209] Also, such conduct may be found to have the effect of substantially lessening competition in violation of Section 7 of the Clayton Act.[210] Accordingly, many of the fears of patent suppression, monopoly pricing, and other antitrust issues may be alleviated by mandating reasonable licenses.

Such a remedy, however, has its problems and fails to address the central issue. A reasonable licensing fee may be difficult to determine and will likely result in further litigation. The problem with a *sui generis* proposal is that it ignores, purposefully or accidentally, the ultimate issue involved—what purpose is served by the enactment of § 287(c). Although a patchwork revision to the patent laws might satisfy the lobbyists, patent aficionados would be left frustrated. Adherence to existing safeguards within patent law affords the right resolution.

VI. CONCLUSION

The enforceability of medical procedure patents should be revisited and rectified. The resolution, as some suggest, might not be merely a restoration of the old law that allowed per se enforcement of medical procedure patents. Perhaps the correct resolution may be creating a framework that satisfies both sides of the controversy, and is true to the theoretical and economic underpinnings of patent law as it has existed for hundreds of years. Such appeasement, however, seems superficial and reeks of a Washington-esque compromise. In this Author's opinion, the current standards of patentability and expected revisions to the patent laws will sufficiently the compelling ethical arguments made by physicians, politicians, and medical associations.

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203. Noonan, *supra* note 63, at 656-57, 664.
204. *See* United States v. Glaxo Group Ltd., 410 U.S. 52, 176 U.S.P.Q. (BNA) 289 (1973).
205. *See* 42 U.S.C. § 2183.
206. *See id.* § 7608.
207. *See* 7 U.S.C. § 2404.
208. *See* 15 U.S.C. §§ 1-7.
209. *See* United States v. Singer Mfg. Co., 374 U.S. 174, 137 U.S.P.Q. (BNA) 808 (1963).
210. *See* 15 U.S.C. §§ 12-27; United States v. Lever Bros., 216 F. Supp. 887 (S.D.N.Y. 1963).

The recent amendment is misguided because patent law is too sophisticated to be altered according to a sudden flash of conventional wisdom that is as much emotional as it is here-today-gone-tomorrow.[211] Although the current law may be a collateral casualty of business as usual in Washington, it is unfortunate that such a controversial and intellectually provocative issue was not afforded the debate that it richly deserved.

SCOTT D. ANDERSON

211. Recently, another medical procedure patent appears to be heading to litigation. Greg Borzo, *Lawsuit Heats Up Over Patent on Common Prenatal Test*, (last modified Jan. 12, 1998) <http://www.ama-assnorg/sci-pubs/amnews/pick_98/pick0112.htm> (discussing a test that is administered to pregnant women for Down syndrome and other congenital disabilities).